UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA WHEELING DIVISION

CITY OF WELLSBURG, BARBOUR COUNTY COMMISSION, BERKELEY COUNTY COMMISSION, GRANT COUNTY COMMISSION, HARDY COUNTY COMMISSION, JEFFERSON COUNTY COMMISSION, MINERAL COUNTY COMMISSION, MORGAN COUNTY COMMISSION, PRESTON COUNTY COMMISSION, POCAHONTAS COUNTY COMMISSION, TAYLOR COUNTY COMMISSION, TUCKER COUNTY COMMISSION, WEBSTER COUNTY COMMISSION, TOWN OF ADDISON, TOWN OF BELINGTON, CITY OF CHARLES TOWN, CITY OF GRAFTON, TOWN OF JUNIOR, CITY OF PHILIPPI, **CLAY COUNTY COMMISSION,** LINCOLN COUNTY COMMISSION, MASON COUNTY COMMISSION, MCDOWELL COUNTY COMMISSION, MERCER COUNTY COMMISSION, MINGO COUNTY COMMISSION, MONROE COUNTY COMMISSION, **PUTNAM COUNTY COMMISSION,** RALEIGH COUNTY COMMISSION, SUMMERS COUNTY COMMISSION, CITY OF LEWISBURG, VILLAGE OF BARBOURSVILLE, TOWN OF CHAPMANVILLE, TOWN OF DELBARTON, TOWN OF GILBERT, TOWN OF HAMLIN, TOWN OF KERMIT, TOWN OF MATEWAN,

Civil Action No. 5:25-cv-00164

Judge John Preston Bailey United States District Judge

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

CITY OF MULLENS, TOWN OF OCEANA, CITY OF POINT PLEASANT, CITY OF WELCH, TOWN OF WEST HAMLIN, and CITY OF WILLIAMSON,

Plaintiffs,

VS.

EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL ORDER PROCESSING, INC.; ESI MAIL PHARMACY SERVICE, INC.; EXPRESS SCRIPTS PHARMACY, INC.; EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.; EXPRESS SCRIPTS SALES OPERATIONS, INC.; EVERNORTH HEALTH, INC.; EVERNORTH CARE SOLUTIONS, INC.; EVERNORTH BEHAVIORAL HEALTH, INC.; and EVERNORTH SALES OPERATIONS, INC.,

Defendants.

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COMPLAINT

I. Introduction

There is an immediate hazard to public health and safety arising out of an opioid¹ 1. epidemic throughout West Virginia including each of the jurisdictions and communities of the named Plaintiffs CITY OF WELLSBURG, BARBOUR COUNTY COMMISSION, BERKELEY COUNTY COMMISSION, GRANT COUNTY COMMISSION, HARDY COUNTY COMMISSION, JEFFERSON **COUNTY** COMMISSION, MINERAL COUNTY COMMISSION, MORGAN COUNTY COMMISSION, PRESTON COUNTY COMMISSION, POCAHONTAS COUNTY COMMISSION, TAYLOR COUNTY COMMISSION, TUCKER COUNTY COMMISSION, WEBSTER COUNTY COMMISSION, TOWN OF ADDISON, TOWN OF BELINGTON, CITY OF CHARLES TOWN, CITY OF GRAFTON, TOWN OF JUNIOR, CITY OF PHILIPPI, CLAY COUNTY COMMISSION, LINCOLN COUNTY COMMISSION, MASON COUNTY COMMISSION, MCDOWELL COUNTY COMMISSION, MERCER COUNTY COMMISSION, MINGO COUNTY COMMISSION, MONROE COUNTY COMMISSION, PUTNAM COUNTY COMMISSION, RALEIGH COUNTY COMMISSION, SUMMERS COUNTY COMMISSION, CITY OF LEWISBURG, VILLAGE OF BARBOURSVILLE, TOWN OF CHAPMANVILLE, TOWN OF DELBARTON, TOWN OF GILBERT, TOWN OF HAMLIN, TOWN OF KERMIT, TOWN OF MATEWAN, CITY OF MULLENS, TOWN OF OCEANA, CITY OF POINT PLEASANT, CITY OF WELCH, TOWN OF WEST HAMLIN, and CITY OF WILLIAMSON (collectively "Plaintiffs").

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¹ As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

- 2. Plaintiffs, including their respective jurisdictions, locality, surrounding areas, and residents in those areas (collectively "Plaintiffs' Communities") are ground zero for the epidemic that is sweeping the nation and continuing to ravage Plaintiffs' Communities.
- 3. This case arises from that devastating epidemic of human creation—the over-prescription, over-supply, misuse, diversion, and abuse of opioids—and the central role that one of the nation's largest Pharmacy Benefit Managers ("PBMs"), Express Scripts, and its affiliates, have played in that epidemic.
- 4. Plaintiffs bring this civil action to eliminate the hazard to public health and safety, to abate the public nuisance caused by the opioid epidemic in each of their respective Communities and for damages sustained as a result of the opioid epidemic proximately caused by Express Scripts, Inc.; Express Scripts Administrators, LLC; Medco Health Solutions, Inc.; ESI Mail Order Processing, Inc.; ESI Mail Pharmacy Service, Inc.; Express Scripts Pharmacy, Inc.; Express Scripts Specialty Distribution Services, Inc.; Express Scripts Sales Operations, Inc.; Evernorth Health, Inc. (formerly Express Scripts Holding Company); Evernorth Care Solutions, Inc.; Evernorth Direct Health, LLC; Evernorth Behavioral Health, Inc.; and Evernorth Sales Operations, Inc. (collectively "Express Scripts").
- 5. The opioid epidemic was caused and sustained by several actors in the prescription opioid supply and payment chain, including the opioid manufacturers, prescription drug distributors, pharmacies, and Express Scripts. Express Scripts' role in causing the opioid epidemic has been, until recently, largely concealed. Now it is clear Express Scripts has, for at least the last two decades, played a central role in causing the oversupply of opioids in Plaintiffs' Communities through actions intended to avoid safeguards in order to increase the prescribing, dispensing, sale, and supply of prescription opioids in Plaintiffs' Communities. Express Scripts intentionally

inserted itself into the chain of distribution and dispensing of prescription opioids, and thereby assumed duties to act reasonably and to comport with the Controlled Substance Act ("CSA") and other applicable laws.

- 6. Express Scripts plays a central role in prescription drug dispensing through contracts it maintains with manufacturers of prescription drugs, pharmacies who dispense prescription drugs, and third-parties who pay for prescription drugs. Express Scripts' conduct which caused the oversupply of opioids included, without limitation: (a) colluding with, and aiding and abetting, Purdue Pharma and other prescription opioid manufacturers in the fraudulent and deceptive marketing and oversupply of prescription opioids; (b) colluding with Purdue Pharma and other prescription opioid manufacturers to increase prescription opioid sales through favorable placement on national formularies in exchange for rebates and fees; (c) colluding with Purdue Pharma and other prescription opioid manufacturers to eliminate or limit utilization management measures on national formularies that would have restricted opioid prescribing; (d) intentionally failing to properly and diligently implement effective drug utilization review measures; (e) failing to undertake reasonable and feasible measures to limit the supply of prescription opioids even though they possessed vast amounts of information about the existence of the opioid epidemic across the United States, including in Plaintiffs' Communities; and (f) dispensing vast quantities of prescription opioids through their mail-order pharmacies without proper controls against diversion, as required by the Controlled Substances Act and West Virginia law.
- 7. Express Scripts is legally responsible for its role in causing, contributing to, and maintaining the opioid epidemic because, *inter alia*: (a) its conduct in colluding with the prescription opioid manufacturers to increase the supply of prescription opioids through false and fraudulent misrepresentations was intentional and/or negligent, as well as unlawful; (b) it

represented and undertook to offer formularies, utilization management protocols, and drug utilization review measures designed to ensure safe and appropriate use of prescription opioids, and then in direct contravention of these measures, wrongfully worked with prescription opioid manufacturers to increase the supply of prescription opioids without regard to the safety or appropriateness of the drugs; (c) it intentionally and/or negligently offered formularies, utilization management protocols, and drug utilization measures that placed no meaningful restrictions on the prescribing and dispensing of prescription opioids despite knowing, through the data they possessed, that (i) such unrestricted access to prescription opioids was causing, and foreseeably would continue to cause, harm (including the foreseeable harm of diversion) to Plaintiffs and their respective Communities, and (ii) those harms could be addressed through measures that Express Scripts intentionally decided not to make available, (d) its conduct with respect to opioid prescribing and dispensing was unlawful as well as intentional and/or negligent because they failed to comply with the Controlled Substances Act and West Virginia law, both in their own dispensing through their mail-order pharmacies and in their other activities that increased the risks of diversion; and (e) it unlawfully controlled association-in-fact enterprises with prescription opioid manufacturers and others through a pattern of racketeering activity, as defined in the federal Racketeer-Influenced and Corrupt Organizations Act ("RICO)").

- 8. Express Scripts' role in the opioid epidemic was made possible by its unique combination of contractual responsibilities, knowledge, and power that placed it in an extraordinarily unique position to control the supply of prescription opioids throughout the United States.
- 9. PBMs such as Express Scripts provide services to prescription drug benefit plans sponsored by health insurers, self-insured employers, and state and federal government agencies.

Express Scripts collects and maintains (and sells) unprecedented amounts of data about the extent of opioid prescribing, far exceeding what any individual manufacturer, distributor, or pharmacy chain has access to. For as long as it has been a PBM, Express Scripts has received, analyzed, and tracked detailed claims data for the billions of prescriptions it processes each year, including opioid prescriptions. Controlling prescription drug benefits for 160+ million Americans, Express Scripts is in possession of detailed information about every prescription it processes, regardless of which company manufactured the drug, which doctor prescribed it, what pharmacy it was filled at, or which city, county or jurisdiction it was dispensed in. It knows when patients whose benefits it manages fill opioid prescriptions written by multiple doctors, when they fill them at multiple pharmacies, and when they refill them early. It knows how many times every opioid prescription it covers is refilled and it knows when a patient who is prescribed opioids is treated for substance use disorder. It knows if one of its covered lives is having prescriptions filled for opioids, benzodiazepines, and sleep aids concurrently. In short, Express Scripts has had a unique vantage point on prescription opioid use and prescribing patterns and associated misuse. Express Scripts quite literally tracked the opioid epidemic across American and in each Plaintiff's Community, pill by pill, as it unfolded over the last two decades.

- 10. Express Scripts is not only in possession of massive amounts of information about opioid prescribing, but it also has the power to encourage and/or drive prescribing, dispensing, and sales of prescription drugs.
- 11. Express Scripts is able to encourage and influence prescribing, dispensing, and sales primarily through the national formularies it offers to pharmacy benefit plans and through what it chooses to offer in terms of standard "utilization management" ("UM") rules. Formularies are lists of drugs covered by a pharmacy benefit plan. Formularies control which drugs are

available to the PBMs' covered lives. They are often constructed in tiers, where drugs listed on higher tiers require larger copays, or as so-called exclusionary formularies, where preferred brand drugs are included and nonpreferred drugs are not included. Standard UM programs include various protocols for managing access and use of particular drugs, including: (i) step therapy, where a beneficiary is required to try a different drug or therapy first before trying the restricted drug; (ii) quantity limits, which are limits on the dosage or days' supply that a patient may receive for any given prescription(s); and (iii) prior authorizations, or ("PAs"), which are rules that require a physician to confirm that a given prescription is therapeutically appropriate before the drug is dispensed. Data shows that, when implemented, disfavored formulary placement and UM reduce inappropriate prescribing by making non-preferred drugs and/or drugs subject to UM restrictions more difficult and more costly to obtain. By contrast, Express Scripts and the prescription opioid manufacturers knew that favorable formulary placement and the absence of UM restrictions create a scenario where prescriptions are written and dispensed with ease and frequency, at the expense of public safety.

- 12. Through its formulary and UM tools, and the other powers at its disposal, Express Scripts, in conjunction with prescription opioid manufacturers, are and have been uniquely situated to influence and control the prescribing and dispensing of opioids to their 160+ million covered lives. Indeed, opioids that are preferred on PBM formularies have significantly greater sales than drugs that are either excluded or disadvantaged. In this regard, Express Scripts act as the gatekeeper to the prescription opioid market.
- 13. Express Scripts has used its hugely profitable role to grow into a vertically integrated colossuses that has come to dominate access to prescription drugs—currently sitting at

twelfth on the Fortune 500 list ranking of the largest corporations in America by revenue. Express Scripts surpassed \$100 billion of annual revenue as early as 2017.

- 14. This corporate leviathan is: (1) one of the three largest PBMs in the United States, managing prescription drug coverage for approximately 160+ million covered lives and processing more than 1.5 billion claims per year; (2) one of the top five dispensing pharmacies in the United States; (3) owned by one of the largest insurance companies in the world (Cigna); and (4) among the largest healthcare data, consulting, and analytics companies in the United States.
- 15. Instead of using its vast stores of information and extensive power to do what it promised its clients and represented to the public—i.e., manage the floodgates of opioid prescribing and limit abuse of these dangerous drugs—Express Scripts worked with the prescription opioid manufacturers to negotiate contracts and structure formulary and UM offerings that encouraged opioid prescribing, facilitating easy and inexpensive dispensing and sales of those drugs. The result of this conduct was that the market for prescription opioids grew, prescribing, dispensing and sales increased, and Express Scripts and prescription opioid manufacturers reaped the profits of their contracts and relationships. For Express Scripts, the profits came from rebates and fees it earned from the branded prescription opioid manufacturers by making prescription opioids freely available and from pricing spreads and fees it captured from generic prescription opioid sales. Profits also came through the sale of critical data and access to and about PBM covered lives and the health care providers who cared for them.
- 16. Not only did Express Scripts aid and abet the manufacturers through their proopioid formulary and UM offerings, but it also colluded with the manufacturers in spreading fraudulent misrepresentations about the risks and benefits of prescription opioids. Express Scripts fraudulently induced doctors to write more opioid prescriptions, and then made sure it would be

easy for patients to fill those prescriptions, thus ensuring an unfettered flow of prescription opioids into communities across America, including in each of Plaintiff's respective Communities.

- 17. Express Scripts' conduct directly contradicted the fact that prior to approximately 1997, Express Scripts recognized the dangers of opioids and had installed various routine controls on quantity and access. At that time, opioids were prescribed infrequently and generally only for either acute pain, calling for very short-term use, or for end-of-life cancer pain.
- 18. In the mid-1990's, Purdue Pharma ("Purdue") introduced OxyContin and began a campaign fraudulently to portray OxyContin as safe and effective for a variety of conditions, including chronic non-cancer pain calling for long-term use. Purdue set out to convince doctors, the medical establishment, and the public generally that opioids are not addictive when taken for pain, regardless of the dose or duration of the therapy. Over time, other opioid manufacturers introduced similar products, first branded opioid drugs and then generic ones, and joined in the campaign fraudulently to increase opioid prescribing.
- 19. Express Scripts' predecessor Medco, which was, in the late 1990's, the largest customer for Purdue's opioids, initially placed a strict quantity limit (80 mg/day) on OxyContin when it was introduced in 1996 and sent letters to prescribers stating that it would not pay for prescriptions for non-cancer pain treatment ("Medco prescriber letters").
- 20. The Medco prescriber letters were a serious threat to Purdue and to other prescription opioid manufacturers. The prescription opioid manufacturers knew that they could not expand the prescription opioid market and flood communities with their products without preferred, unrestricted access to their opioids on Express Scripts' formularies.
- 21. Recognizing the unique role that Express Scripts plays as a gatekeeper of the pharmaceutical market, Purdue set out to change Express Scripts' policies about OxyContin and

about opioids generally. Purdue did this not (or not primarily) by convincing Express Scripts that OxyContin was safe and effective for the treatment of chronic non-cancer pain—which it is not—but rather by convincing Express Scripts it could make vast amounts of money by allowing unrestricted access to prescription opioids.

- 22. In a January 1997 email to Purdue's president Dr. Richard Sackler (and others) responding to the Medco prescriber letters, Michael Friedman, who would later become Purdue's CEO, stated, "This is a serious matter that we cannot ignore and that we must discuss. . . We cannot go on ignoring the reality of [Express Scripts'] economic proof requirements . . . If we are to stay in business we need proof of economic performance." (Emphasis added.) Purdue thus understood that for OxyContin to succeed, it would have to show Express Scripts that increasing opioid use would be to its economic benefit.
- 23. This was a critical moment in the creation and subsequent spreading of the opioid epidemic. If Medco—Purdue's largest customer—had excluded OxyContin from its formularies or restricted its use to palliative care and/or cancer pain in 1997 (as it should have), OxyContin would never have become widely available, other branded prescription opioids and generics never would have followed the OxyContin wave, and the opioid epidemic would likely never have happened.
- 24. Medco, however, failed to take such actions. Instead, Medco became knowing and willing partners with Purdue and the other prescription opioid manufacturers at this critical juncture because it knew that increasing opioid supply and use would be more profitable for it. Medco/Express Scripts was able to profit from such increased supply and use because their agreements with the prescription opioid manufacturers provided for rebates and "administrative fees" to be paid for each rebate-eligible opioid prescription adjudicated by Medco/Express Scripts.

Thus, every dollar spent on prescription opioids would put money in Express Scripts' pockets.

When a drug was given "preferred" status on a formulary, the rebates were higher.

- 25. Within months of sending its prescriber letters warning about the dangers of OxyContin, Medco completely reversed course and informed Purdue that it had become "very interested in partnering with Purdue." Medco doubled its initial quantity limits from 80 mg/day to 160 mg/day within the first year of OxyContin's release. By 2000, Medco again doubled this limit to 320 mg/day (*four times* the limit that Medco originally determined was medically appropriate for OxyContin). To make its formulary changes more effective, Medco worked "behind the scenes" with Purdue to persuade several of Medco's largest clients to lift any restrictions they had (such as prior authorizations and quantity limits) on OxyContin sales.
- 26. But it wasn't enough for Medco to just lift restrictions on the filling of opioid prescriptions (open the floodgates); it also worked with Purdue to increase the number of opioid prescriptions written (increase the flow of water at the source). To that end, it joined forces with Purdue on numerous marketing campaigns, assisting Purdue in its dissemination of fraudulent misrepresentations about the safety and efficacy of prescription opioids for a wide variety of conditions for which the drugs had previously been understood to be dangerous and unsuitable. This included mailings to prescribers fraudulently promoting OxyContin as safe and effective and only very rarely leading to abuse and/or addiction.
- 27. For years Medco and Express Scripts worked directly with Purdue to disseminate misinformation about OxyContin. These efforts included Express Scripts using its own "proprietary database" to locate high prescribers of opioids and then "blasting" these physicians with materials created by Purdue-paid front groups that promoted myths about the use of opioids that they knew had no basis in fact. It did this to overcome the resistance doctors had to prescribing

dangerous opioids. In a particularly telling exchange, Express Scripts informed Purdue that these efforts were necessary "so that [Express Scripts] may squelch the anti-OxyContin pushback from [Express Scripts] clients . . . due in large part to the [negative] national media attention OxyContin

- 28. None of what Express Scripts represented about opioids' effectiveness and necessity for treating chronic pain, their cost and clinical benefits, or the unlikelihood of their leading to addiction for patients in long term opioid therapy, was true, and it knew it.
- 29. In fact, prescription opioids are highly addictive, even in patients taking them for pain, and the risk of abuse increases at higher doses and longer durations. Moreover, prescription opioid therapy is not, in fact, particularly effective for chronic pain. Increased prescribing of opioids, for longer periods and at higher doses, and without the scrutiny that would accompany use of a drug whose risks were properly understood, would inevitably lead to increases in the number of individuals suffering from opioid use disorder ("OUD"), the clinical name encompassing the condition sometimes referred to popularly as addiction.
- 30. Express Scripts' partnership with Purdue to expand the prescription opioid market was successful: in the years following its release, OxyContin sales exploded—growing from \$48 million in 1996 to \$1.6 billion by 2003—and drove a huge nationwide spike in overall opioid prescribing. During this same time, the annual number of OxyContin prescriptions for non-cancer pain increased nearly tenfold, from about 670,000 in 1997 to about 6.2 million in 2002.
- 31. As a direct result of Express Scripts' and Purdue's coordinated efforts, prescription opioid use and abuse escalated to epidemic levels by the mid-2000s, devastating communities across the country and West Virginia, including in each Plaintiff's Community. Plaintiffs have

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is receiving."²

² PPLPC029000040033.

been dealing with the public health crisis caused by Express Scripts' misconduct for the past two decades.

- 32. Making matters worse, having helped launch the opioid epidemic, Express Scripts then failed to close the floodgates despite knowing that prescription opioids were causing a public health crisis. Its data showed what was happening, and it had the tools to fix it. But for years, Express Scripts failed to address the opioid epidemic it helped create. Even as the federal government started requiring certain controls be put in place in federal health plans, Express Scripts deliberately chose not to offer similar controls to their commercial clients with the full knowledge that such a choice would lead to continued prescription opioid oversupply, diversion, addiction, abuse, and death.
- 33. As the opioid epidemic spread throughout the country and West Virginia, including Plaintiffs' Communities, Express Scripts intentionally chose not to undertake actions that it knew would have drastically reduced the inappropriate prescribing and dispensing of opioids, such as enacting effective UM protocols or disadvantaging opioids on their formularies. For example, for nearly every year for the past 20+ years, Express Scripts preferred OxyContin on its formularies over safer, more effective, forms of pain treatment.
- 34. Express Scripts chose not to limit access to prescription opioids—including both branded and generic drugs—because with the prescription opioid manufacturers, they had formed an agreement to do everything in their power to grow the market for prescription opioids without regard for public safety in order to profit from the sales of these drugs generated for Express Scripts and the opioid manufacturers. Over at least the last two decades, Express Scripts has received millions of dollars in rebate payments from the prescription opioid manufacturers in exchange for actions and omissions that incentivized and facilitated easy prescribing of prescription opioids (via

favorable formulary and UM decisions) and led to unrestricted dispensing of those same drugs (through DUR decisions).

- 35. Express Scripts now publicly admits that it was "uniquely situated" to stop the opioid epidemic and that they can create UM protocols that can "ensure that physician prescribing and pharmacy dispensing is in line with the most-up-date scientific evidence and national consensus guidelines." The power that it now admits possessing is the same power that allowed it to aid and abet with the opioid manufacturers to drive the oversupply of opioids through increases in prescribing and dispensing.
- 36. Express Scripts has always had the ability to offer and the power to employ interventions that would minimize inappropriate opioid prescribing, dispensing, use, and abuse and thereby to prevent the progression of the opioid epidemic. Yet it failed to do so, not only at the outset of the opioid crisis, in the 1990's, but for two decades after that, as it watched the opioid crisis steadily unfold.
- 37. Despite knowing that prescription opioids were highly addictive, overused, and heavily abused, for over two decades Express Scripts intentionally did little to curb inappropriate prescribing, diversion, and abuse—instead, standing by while retail pharmacies (as well as their own mail order pharmacies) dispensed wildly excessive quantities of opioid prescriptions.
- 38. From their own data alone, Express Scripts could see that prescription opioids were far more addictive and dangerous than what Purdue and the other opioid manufacturers had been telling the medical community and the public. It could see from its own data that the drugs required greater restrictions on access than they had led their clients to believe. But Express Scripts had much more than just its own data to tell them it what it had been saying, and the false narrative that had been guiding its formulary and UM offerings, was untrue (even assuming they had ever

believed it): in May, 2007, Purdue pleaded guilty to federal charges of criminal misbranding with respect to OxyContin. It paid a \$635 million fine and entered into a Corporate Integrity Agreement that required it to ensure that its marketing of OxyContin would be fair and accurate. (Following its entry into this agreement, Purdue promptly contracted with McKinsey & Co. for advice as to how to continue to increase OxyContin sales.) As part of its plea agreement, in an agreed statement of facts, Purdue agreed that it had "with the intend to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications. . . ." The agreed statement of facts detailed the ways in which Purdue's marketing had been false and misleading.

- 39. Thus, regardless of what it knew before Purdue entered into its plea agreement in May 2007, once that agreement was made public, Express Scripts had actual and specific knowledge that the marketing activities on which it had colluded with Purdue (and with other opioid manufacturers) were fraudulent, leading to dangerous opioid oversupply and death in Plaintiffs' Communities. It also had certain knowledge that any supposed justifications for its formularies and UM offerings regarding prescription opioids—that the drugs were appropriate for prescription with minimal scrutiny, that they should be made available for a wide variety of conditions and for extended, long-term therapy without intensive scrutiny and review—were lies. Yet it would be approximately *ten more years* before Express Scripts changed its national formulary and UM offerings to place meaningful restrictions on drugs it certainly knew were too dangerous to be prescribed, dispensed, and used as freely as Express Scripts and Purdue had led people to believe they could be.
- 40. Rather than use its granular claims data to limit problematic opioid use or investigate outlier prescribing patterns, Express Scripts sold its data to third-party vendors who in

turn resold the data to opioid manufacturers, including Purdue, who used the data to aid their marketing, so that they could continue to stoke increased prescribing of opioid drugs.

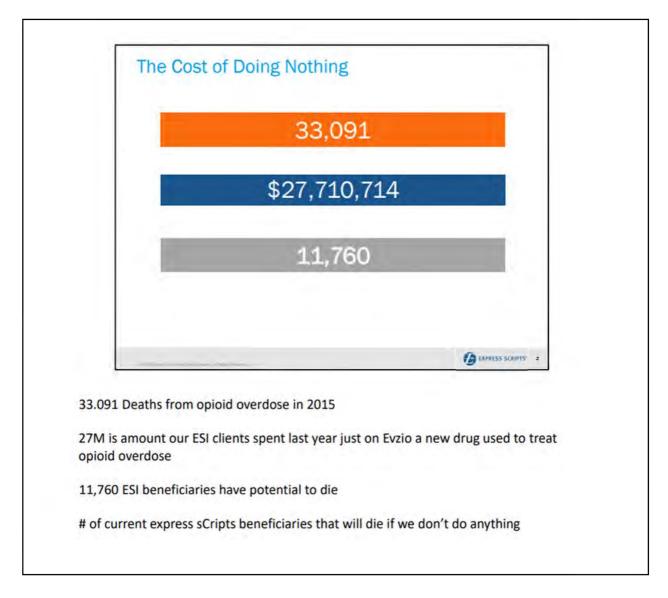
- 41. Express Scripts played an additional role in creating the opioid crisis in Plaintiffs' Communities. By virtue of operating its huge mail-order pharmacies, Express Scripts was often the entity that dispensed the drugs (that is, filled prescriptions), a role that imposed on it affirmative duties to provide controls against diversion of these dangerous drugs. The data in its possession, both from its dispensing activities and from its prescription management activities across virtually every retail pharmacy in the nation (over approximately 60,000 in its network), provided sufficient information and insight into patterns of prescribing to enable it to provide the controls that were required by law. Express Scripts failed, however, to use this data to implement such controls. Instead, Express Scripts sold the data to the opioid manufacturers for them to use in their marketing efforts to *increase* sales of prescription opioids, without regard to the effects of such increases on the potential diversion of these drugs.
- 42. Express Scripts' mail-order pharmacies have operated within the federally-regulated closed system for controlled substances. Despite its obligations under the Controlled Substances Act to provide controls against diversion and to dispense opioids only pursuant to valid prescriptions issued for a legitimate medical purpose, Express Scripts dispensed billions of morphine milligram equivalents ("MMEs") (the standard measure used when measuring quantities of opioids of different strengths) of opioids into communities across the country, including Plaintiffs' Communities, often without adequate due diligence to ensure that the prescriptions involved were valid and not likely to be diverted.
- 43. Express Scripts is registered with the Drug Enforcement Administration ("DEA") as a dispenser and, by registering, is required to provide effective controls against diversion. But

it failed to provide the requisite controls with respect to all of its activities that affect dispensing. And in its business practices as a PBM, it intentionally and/or negligently ignored the risks of diversion and even, at times, increased them. Even though Express Scripts used separate entities to perform its mail-order pharmacy and PBM functions, Express Scripts was required by the CSA to provide effective controls against diversion across all of its activities that affect dispensing, whether as a mail-order pharmacy or otherwise. Express Scripts' failure to do so was in violation of the CSA.

- 44. Express Scripts thus has not been a mere bystander in the opioid crisis; rather, it colluded with the opioid manufacturers, placed profits over safety, and engaged in a clandestine and fraudulent scheme to increase the sale of prescription opioids, despite the known dangers of these drugs.
- 45. It was only well after the opioid epidemic reached its peak, and after the U.S. Senate and state governments began to investigate Express Scripts' role in causing the opioid epidemic, that Express Scripts finally began to implement UM measures to address the public health crisis behind which they were a driving force.
- 46. Notably, when Express Scripts finally took meaningful steps to address the epidemic by enacting opioid management programs many years later, the results were significant. Express Scripts' own data shows that, following the implementation of its opioid management programs, opioid prescribing and use, as measured by multiple metrics, significantly decreased across the populations of lives it covers.
- 47. Express Scripts could have implemented those same opioid management measures at any point over the past two decades. Had it put in place the tools that it knew would have reduced opioid overuse—such as those implemented it more recently implemented—when they first knew

these drugs were causing a public health crisis, it would have had a substantial impact on addressing the opioid epidemic.

48. Express Scripts' own marketing material shows with shocking precision the effect that Express Scripts' delay had on its covered lives. A March 2017 Express Scripts PowerPoint titled "Comprehensive Opioid Solution: What is Express Scripts Doing to Combat this Epidemic?" included the following slide that detailed Express Scripts' calculation of how many of its own covered lives would die in the future if Express Scripts did nothing to combat the opioid epidemic:



- 49. Express Scripts said nothing about the covered lives that had *already* been lost through its inaction over the decade or more that Express Scripts sat idly by and watched the opioid epidemic escalate across the country and in Plaintiffs' Communities. But its ability to calculate with such precision the number of such lives going forward speaks volumes both about its earlier failures to act and about the likely scale of the losses attributable to those failures.
- 50. Express Scripts' scheme has had far-reaching public health consequences, the costs of which have been borne by communities across the United States and West Virginia, including in each Plaintiff's respective Community.
- 51. According to the United States Centers for Disease Control and Prevention ("CDC"), prescription opioids have directly and indirectly accounted for more than 80% of overdose deaths in the United States, a toll that has quadrupled over the past two decades. More people have died from opioid-related causes than from car accidents or guns. More than 175 people die every day from opioid overdoses—as if an airplane were to crash, killing everyone on board, every day.
- 52. The epidemic's economic costs for healthcare, lost productivity, addiction treatment, and criminal justice involvement is estimated at \$1.02 trillion a year.
- 53. The devastating human toll of opioid abuse cannot be overstated. After years of decreasing death rates in the United States, these rates are now on the rise, fueled in no small part by an increase in opioid-related drug overdose deaths. Drug overdoses are now the leading cause of death for Americans under the age of fifty. The number of Americans who died of drug overdose deaths in 2017 alone was roughly equal to the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.

- 54. From 1999 through the present, over 1,000,000 people have died from an overdose involving opioids. Well over half of those deaths involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Nucynta, Duragesic, Subsys, Actiq, and Fentora, which were manufactured respectively by Purdue, Endo, Janssen/J&J, Insys, and Teva/Cephalon. The drugs also include generic opioids such as hydrocodone, oxycodone, fentanyl, hydromorphone, morphine, methadone, tapentadol, and oxymorphone manufactured by Teva, Mallinckrodt and other generic drug makers.
- 55. The opioid epidemic rages on to this day in Plaintiffs' Communities and continues to worsen each year. Across the country, a staggering 110,000 people died of opioid overdoses in 2022 alone.
- 56. For many of the people whose lives were cut short by opioid overdoses, even if the drug used at the time of overdose was a non-prescription opioid such as heroin or illicit fentanyl, their opioid use began with prescription pills. Many opioid users, having become addicted to, but no longer able to obtain prescription opioids, turn to heroin. According to the American Society of Addiction Medicine, 80% of the people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. Both heroin and oxycodone, for example, are semisynthetic derivatives of naturally occurring alkaloids found in opium; heroin—or diacetylmorphine—is derived from morphine. Unsurprisingly, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. In recent years, individuals have become addicted to even stronger opioids, often turning to illicit fentanyl, with even more lethal effects.

- 57. According to Robert Anderson, who oversees death statistics at the CDC: "I don't think we've ever seen anything like this. Certainly not in modern times." On October 27, 2017, then-President Trump declared the opioid epidemic a public health emergency. On December 22, 2022, Health and Human Services Secretary Xavier Becerra renewed the determination that the "opioid public health emergency exists nationwide."
- 58. On August 11, 2017, Governor Jim Justice similarly proclaimed that "we have a national public health emergency when it comes to opioid use" and that "we have an emergency in West Virginia with opioid and drug addiction. This devastating scourge is taking the lives of hundreds of our citizens every year."
- 59. West Virginia is experiencing a drug overdose epidemic which is causing devastating socio and economic consequences. As in many other communities in the United States, opioid use has been and continues to be at crisis levels in Plaintiffs' Communities.
- 60. Express Scripts' conduct has had severe and far-reaching consequences for public health, social services, and criminal justice, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiffs. These necessary and costly responses to the opioid crisis in Plaintiffs' Communities include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarcerations, treating opioid-dependent newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placement, among others.
- 61. Plaintiffs' resources and abilities have been strained to the breaking point by this public health crisis, which has an impact on all of the services they provide their citizens. The burdens imposed on Plaintiffs are not the normal or typical burdens of governmental programs and

services. Rather, these are extraordinary costs and losses that are directly related to Express Scripts' conduct.

- 62. The losses inflicted have cut across ages and generations. Many who have succumbed to overdoses have overdosed more than once. Family members, including young children, have watched their loved ones lose consciousness or die. Young children, including toddlers, also have been the direct victims of overdoses themselves after coming into contact with opiates, often being addicted at birth by an addicted mother.
- 63. The resulting plague has meant that hundreds of children have been displaced from their homes and have been raised by relatives or placed in public care due to their parents' addiction. Others lose the chance to go home. Unable to be discharged from the hospital with their mothers, hundreds of babies who have been born addicted to opioids due to prenatal exposure have been placed in the care of public resources or local citizens or non-profits who do their best to comfort them through the pain of withdrawal.
- 64. Currently, West Virginia's foster care system is in a crisis with more than 6,000 kids in the foster care system. West Virginia has the highest rate of children in foster care—a figure that's four times higher than that of the United States as a whole. This is largely attributable to the opioid epidemic which has caused West Virginia's foster care population ballon by 57% over the past decade, overwhelming an already strapped child welfare system.
- 65. Individually, and colluding with opioid manufacturers, Express Scripts caused, contributed to, and maintained the opioid crisis and now must abate the ongoing public nuisance it created in communities across America, including Plaintiffs' Communities.
- 66. Individually, and colluding with opioid manufacturers, Express Scripts' conduct was a substantial contributing factor in the creation of the opioid crisis, which to this day continues

to unreasonably interfere with the public health, safety, and welfare in each Plaintiff's respective Community and is therefore a public nuisance.

- 67. Express Scripts aided and abetted the fraudulent marketing of prescription opioids.
- 68. Express Scripts and opioid manufacturers formed an association-in-fact enterprise, the "Formulary & UM Enterprise." The common purpose of the Formulary & UM Enterprise was to profit from the increased and unrestricted prescribing, dispensing, and sale of prescription opioids without regard for public safety. Express Scripts conducted, and participated in the conduct of, the Formulary & UM Enterprise by agreeing to not take action that would undercut other PBMs' business; agreeing to work with the opioid manufacturers; agreeing to take and taking formulary action that would motivate and facilitate increased opioid prescribing; agreeing to take and taking UM actions that would facilitate easier and increased opioid dispensing and sales; working with opioid manufacturers to disseminate the false marketing and to support their detailing of prescription opioids to prescribers; and failing to uphold its distribution and dispensing obligations under the Controlled Substances Act and its implementing regulations. All of this conduct furthered the underlying fraudulent scheme of the Formulary & UM Enterprise because it served to deprive people of money and property by means of an underlying fraudulent scheme, including taking actions that directly contradicted the public representations they made about their conduct as well as the promises they made to their clients. Furthermore, Express Scripts has engaged in additional illegal conduct, including filing false statements about their revenue with the Securities and Exchange Commission ("SEC").
- 69. Express Scripts undertook and assumed a duty to create formularies and UM programs based on the health and safety of the public, including Plaintiffs, and of the lives covered by the benefit plans that were their clients. Express Scripts represented to the public, as well as to

their clients, that its formularies and UM offerings were based on the health and safety of the public and the lives its clients insured, when in fact it was doing the exact opposite and was acting to maximize its own revenue in concert with the opioid manufacturers. Express Scripts knew, at the time that it made these representations to the public and to its clients, that it would not base its formularies and UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that it would make, and was already making, formulary and UM decisions, and taking formulary and UM actions, designed solely (or at least primarily) to increase its profits.

- 70. The prescription opioid manufacturers—with whom Express Scripts colluded in creating the opioid crisis—have themselves faced substantial civil and criminal liability for their roles and have agreed to pay billions of dollars to assist with the generational devastation caused by their scheme. A few examples include:
 - (a) In October 2020, the Department of Justice announced that Purdue entered into a federal settlement of more than \$8 billion to resolve pending criminal and civil allegations regarding Purdue's role in causing the opioid epidemic;
 - (b) In February 2022, Janssen/J&J agreed to finalize a proposed \$5 billion settlement resolving claims by states and local governments that they helped fuel the U.S. opioid epidemic;
 - (c) In July 2022, Teva announced it would pay up to \$4.25 billion as part of a nationwide settlement to end litigation over its alleged role in the U.S. opioid crisis; and
 - (d) In August 2022, Endo agreed to pay \$450 million to states to resolve opioid lawsuits across the country.
- 71. Express Scripts, too, should be required to bear the costs of abating the devastating nuisance that they, along with the other entities, brought about in each Plaintiff's Community.
- 72. Plaintiffs bring this suit to hold Express Scripts accountable for the devastating opioid crisis they helped caused, contributed to, and maintained.

II. Jurisdiction and Venue

- 73. This Court has jurisdiction over the subject matter of this case pursuant to 28 U.S.C. § 1331 because Plaintiffs' claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et seq.*, raise a federal question. This Court has supplemental jurisdiction over Plaintiffs' state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.
- 74. This Court independently has subject matter jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1 332(d)(2)(A), because the amount in controversy well exceeds \$75,000.00, exclusive of interest and costs, and Plaintiffs and Express Scripts are citizens of different states.
- 75. This Court has personal jurisdiction over each Defendant because at all relevant times they conducted business in the State of West Virginia, were engaged in substantial business activities in West Virginia and purposefully directed their actions toward the State of West Virginia, carry on continuous and systematic business in West Virginia, are registered to do business in West Virginia and have purposefully availed themselves of the privilege of conducting business within West Virginia, consented to be sued in the State of West Virginia by registering an agent for service of process, consensually submitted to the jurisdiction of the State of West Virginia when obtaining a license to operate as a pharmacy benefit manager within the state of West Virginia, and because they have the requisite minimum contacts with the State of West Virginia necessary to constitutionally permit the Court to exercise jurisdiction.
- 76. This Court also has personal jurisdiction and venue over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiffs demonstrate national contacts.

Here, the interests of justice require that Plaintiffs be allowed to bring the members of the nationwide RICO enterprise before the court in a single trial.

- 77. Venue is proper in this District under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in the Northern District.
- 78. Venue as to each Defendant is also proper in the Northern District of West Virginia under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to Plaintiffs' claims occurred in the Northern District of West Virginia. At all relevant times, Express Scripts contracted to provide pharmacy benefit management, claims processing services, and/or other prescription opioid drug services for health benefit plans and/or insurance companies throughout West Virginia and provided significant services for health plans and/or insurance companies and their members, participants, enrollees, and/or beneficiaries throughout this District and, as recognized by Courts in West Virginia³ as well as the West Virginia legislature, ⁴ events and omissions occurring in the Northern District have far reaching consequences across West Virginia causing harm and damages throughout the State, including in each Plaintiff's Community.
- 79. Given West Virginia's unique geographical and demographic characteristics, and because prescription opioids are highly addictive and have a high abuse potential, the causative nature of the opioid epidemic is and was migratory. As the demand for prescription opioids grew,

³ In Re Opioid Litigation, Civil Action No. 19-C-9000, March 13, 2020 Hearing Transcript, Pt. 16, Lines 8-14 ("Right now we're dealing with a virus. Viruses know no boundaries. From wherever we all came from yesterday, it knows no boundaries. And it's illogical and unreasonable to think that somehow a public nuisance that is alleged to not be in just this state but in every state, somehow stops at the boundaries of the municipality, a county, or a state for that matter.") *Id.*, JA000006 ("The opioid crisis is ubiquitous. It knows no boundaries and is not limited to a specific city or county in West Virginia.") JA000006.

⁴ W. Va. Code § 5-31-1, *et seq*. (adopting and recognizing statewide abatement remedy for opioid funds received in settlement of opioid related litigation).

prescription opioids migrated to, from, and between Plaintiffs' Communities with a high supply and demand throughout Plaintiffs' Communities, thus encompassing and moving all through the entire State of West Virginia, including from Plaintiffs' Communities within this Judicial District to other Plaintiffs' Communities outside this Judicial District through various pathways.

80. By way of example, opioid prescriptions written in Plaintiffs' Communities outside this Judicial District were dispensed in Plaintiffs' Communities within this Judicial District, and vice versa. Additionally, individuals transported prescription opioids from Plaintiffs' Communities within this Judicial District to Plaintiffs' Communities outside this Judicial District, and vice versa, in order to sell, transfer, and/or divert them. In the regular course of the opioid epidemic, prescription opioids migrated between Plaintiffs' Communities within and throughout this Judicial District, and through other parts of West Virginia. Express Scripts was aware of these facts and phenomenon, and their consequences and harm within Plaintiffs' Communities was foreseeable.

III. Parties

A. Plaintiffs

- 81. Plaintiff **CITY OF WELLSBURG** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 82. Plaintiff **BARBOUR COUNTY COMMISSION** ("Barbour County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance."

 W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d

217 (1969); Berkeley Cnty. Comm'n v. Shiley, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Plaintiff **GRANT COUNTY COMMISSION** ("Grant County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 85. Plaintiff **HARDY COUNTY COMMISSION** ("Hardy County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take

"appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982)

(citing Syl. Pt. 1, State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 89. Plaintiff **PRESTON COUNTY COMMISSION** ("Preston County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 90. Plaintiff **POCAHONTAS COUNTY COMMISSION** ("Pocahontas County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety

and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Plaintiff **TAYLOR COUNTY COMMISSION** ("Taylor County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Plaintiff **TUCKER COUNTY COMMISSION** ("Tucker County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982)

(citing Syl. Pt. 1, State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Plaintiff **WEBSTER COUNTY COMMISSION** ("Webster County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 94. Plaintiff **TOWN OF ADDISON** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 95. Plaintiff **TOWN OF BELINGTON** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 96. Plaintiff **CITY OF CHARLES TOWN** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 97. Plaintiff **CITY OF GRAFTON** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

- 98. Plaintiff **TOWN OF JUNIOR** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 99. Plaintiff **CITY OF PHILIPPI** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 100. Plaintiff CLAY COUNTY COMMISSION ("Clay County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982)

(citing Syl. Pt. 1, State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 104. Plaintiff MERCER COUNTY COMMISSION ("Mercer County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and

to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982)

(citing Syl. Pt. 1, State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).
- 109. Plaintiff **SUMMERS COUNTY COMMISSION** ("Summers County") is a West Virginia political subdivision which may sue and plead in its own name and has standing to take "appropriate and necessary actions for the elimination of hazards to public health and safety and

to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a) (2008); W. Va. Code § 7-1-3(a) (2024); W. Va. Code § 29-12A-3(c) (1986); W. Va. Code § 14-2-3 (2017); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969); *Berkeley Cnty. Comm'n v. Shiley*, 170 W. Va. 684, 685-86, 295 S.E.2d 924, 926 (1982) (citing Syl. Pt. 1, *State ex rel. Cnty. Ct. of Cabell Cnty. v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34 (1965)).

- 110. Plaintiff **CITY OF LEWISBURG** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 111. Plaintiff **VILLAGE OF BARBOURSVILLE** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 112. Plaintiff **CITY OF CHAPMANVILLE** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 113. Plaintiff **TOWN OF DELBARTON** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera* v. City of Wheeling, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 114. Plaintiff **TOWN OF GILBERT** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

- 115. Plaintiff **TOWN OF HAMLIN** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 116. Plaintiff **TOWN OF KERMIT** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 117. Plaintiff **TOWN OF MATEWAN** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 118. Plaintiff **CITY OF MULLENS** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 119. Plaintiff **TOWN OF OCEANA** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 120. Plaintiff **CITY OF POINT PLEASANT** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 121. Plaintiff **CITY OF WELCH** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

- 122. Plaintiff **TOWN OF WEST HAMLIN** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 123. Plaintiff **CITY OF WILLIAMSON** is a municipal corporation of the State of West Virginia which may sue and plead in its own name. W. Va. Code § 7-1-1(a) (2008); *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 124. The distribution, sale, and diversion of prescription opioids into West Virginia and into each Plaintiff's Community created the foreseeable opioid epidemic and opioid public nuisance for which Plaintiffs seek relief.
- 125. Plaintiffs provide a wide range of services on behalf of their residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.
- 126. Plaintiffs directly and foreseeably sustained all economic damages alleged herein. Express Scripts' conduct has exacted a financial burden for which Plaintiffs seek relief. Plaintiffs, like any other local government, endeavor in good faith to provide a wide variety of necessary services on a limited budget funded with taxpayer dollars. Express Scripts' conduct has imposed an extraordinary burden on Plaintiffs' limited resources and services for which they seeks relief. These damages have been suffered, and continue to be suffered directly, by Plaintiffs.
- 127. Plaintiffs also seek the means to abate the epidemic created by Express Scripts' wrongful and/or unlawful conduct.
- 128. Plaintiffs have standing to bring this action to protect the public health, safety and welfare of its citizens and to seek appropriate relief for the damages and harm caused by Express Scripts' unlawful and tortious acts and/or omissions.

- 129. Plaintiffs have standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).
- 130. Express Scripts' intentional, negligent, and/or unlawful conduct, alleged more fully herein, has created a serious public health crisis of opioid abuse, addiction, morbidity, and mortality and is a public nuisance in each Plaintiff's Community.
- 131. Express Scripts' conduct is beyond anything Plaintiffs could have prepared for, predicted or avoided. It is a repeated course of conduct that did, does, and will—given the realities of addiction—continue to result in recurring and ongoing harm to Plaintiffs. Express Scripts' conduct is especially malicious when one considers the harm it has wreaked on governmental entities such as Plaintiffs who, in good faith, endeavor to provide a wide variety of necessary services on a limited budget funded with taxpayer dollars. The magnitude of Express Scripts' scheme is neither discrete nor of a sort that a county, city, or local governmental entity, including Plaintiffs, could reasonably expect to have to respond to at any time during its existence as such. It would be unreasonable, unjust, and inequitable not to allocate the additional governmental expenses, and any other costs associated with the harms Express Scripts' wrongful conduct has caused, to the actual parties responsible for creating the need for the resources to be expended as they are and were.

B. Defendants

1. The Express Scripts Defendants

132. **Evernorth Health, Inc.** (f/k/a Express Scripts Holding Company) ("Evernorth") is a Delaware corporation with its principal place of business is at One Express Way, St. Louis, Missouri 63121.

- 133. Evernorth is the parent company to all of the Express Scripts entities named as Defendants in this action. Evernorth, through its executives and employees, controls the enterprise-wide policies that inform all of Express Scripts' lines of business in order to maximize profits across the corporate family.
- 134. At all times material herein, Evernorth was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.
- of business at One Express Way, St. Louis, Missouri 63121. Evernorth Care Solutions, Inc. is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Evernorth Care Solutions, Inc. was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.
- 136. **Evernorth Direct Health, LLC** is a Delaware limited liability company with its principal place of business at One Express Way, St. Louis, Missouri 63121. Evernorth Direct Health, LLC is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Evernorth Direct Health, LLC was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.
- 137. **Evernorth Behavioral Health, Inc.** is a Minnesota corporation company with its principal place of business at 6625 West 78TH Street, Bloomington, MN, 55439. Evernorth Behavioral Health, Inc. is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Evernorth Behavioral

Health, Inc. was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.

- 138. **Evernorth Sales Operations, Inc.** is a Delaware corporation company with its principal place of business at One Express Way, St. Louis, Missouri 63121. Evernorth Sales Operations, Inc. is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Evernorth Sales Operations, Inc. was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.
- 139. **Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts, Inc.'s principal place of business is at One Express Way, St. Louis, Missouri 63121. Express Scripts, Inc. is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313.
- 140. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout West Virginia that engaged in the conduct which gives rise to this Complaint.
- 141. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail order services businesses, including with respect to the at-issue drugs, as well as Express Scripts' data and research services.
- 142. **Express Scripts Administrators, LLC,** is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Administrators, LLC's principal place of business is at the same location as Express Scripts, Inc. Express Scripts

Administrators, LLC is registered to do business in West Virginia and may be served through its registered agent CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313

- 143. Express Scripts Administrators, LLC applied for and holds an active license with the West Virginia Insurance Commissioner to operate as a pharmacy benefits manager in the state of West Virginia.
- 144. During the relevant time period, Express Scripts Administrators, LLC provided PBM services in West Virginia, including in this Judicial District and in Plaintiffs' Communities.
- 145. **Medco Health Solutions, Inc.** (f/k/a Merck-Medco) ("Medco") is a Delaware Corporation with its principal place of business located at One Express Way, St. Louis, Missouri 63121, and is a wholly-owned subsidiary of Evernorth Health, Inc. Medco Health Solutions, Inc. was previously known as Merck-Medco. Merck-Medco was acquired in the early 1990s by Merck & Co. as its pharmacy benefit manager subsidiary. In 2002, Merck & Co. spun off Merck-Medco into a publicly traded company, defendant Medco Health Solutions, Inc.
- 146. Medco Health Solutions, Inc. is registered to do business in West Virginia and may be served through its registered agent: CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Medo Health Solutions, Inc. was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.
- 147. **ESI Mail Order Processing, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. ESI Mail Order Processing, Inc. is not registered to do business in West Virginia but at all times material herein, ESI Mail Order Processing, Inc. was transacting business in West Virginia and its conduct had a direct effect in West Virginia, including

in Plaintiffs' Communities. ESI Mail Order Processing, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

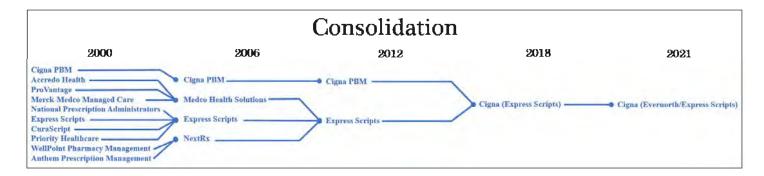
- 148. During the relevant time period, ESI Mail Order Processing, Inc. provided mail order pharmacy services in West Virginia, including in this Judicial District and in each Plaintiff's Community, which gives rise to the causes of action herein.
- 149. **ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Express Scripts, Inc. ESI Mail Pharmacy Service, Inc. may be served through tis registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.
- 150. During the relevant time period, ESI Mail Pharmacy Service provided mail order pharmacy services in West Virginia, including in this Judicial District and in Plaintiffs' Communities, which gives rise to the causes of action herein.
- 151. **Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Express Scripts, Inc. Express Scripts Pharmacy, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.
- 152. During the relevant time period, Express Scripts Pharmacy, Inc. provided mail order pharmacy services in West Virginia, including in this Judicial District and in Plaintiffs' Communities, which gives rise to the causes of action herein.

- 153. Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. are referred to herein collectively as "Express Scripts Mail Order Pharmacy."
- 154. In 2021, Express Scripts Mail Order Pharmacy was the third largest dispensing pharmacy in the United States and reported \$54.4 billion in prescription revenues.
- 155. From 2006 to 2014, Express Scripts Mail Order Pharmacy bought over 22.9 billion MMEs of opioids spread over 1.1 billion opioid dosage units.
- and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Specialty Distribution Services, Inc.'s principal place of business is at the same location as Express Scripts, Inc. Express Scripts Specialty Distribution Services, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.
- 157. During the relevant time period, as alleged in more detail herein, Express Scripts Specialty Distribution Services, Inc. worked directly with the opioid manufacturers to expand the opioid market, including with Purdue and Endo to administer and dispense opioids through these opioid manufacturers' Patient Assistance Programs, including in this Judicial District, Plaintiffs' Communities and West Virginia.
- 158. **Express Scripts Sales Operations, Inc.** is a New Jersey corporation with its principal place of business located at One Express Way, St. Louis, Missouri 63121, and, upon information and belief, is a wholly-owned subsidiary of Evernorth Health, Inc. Express Scripts Sales Operations, Inc. is registered to do business in West Virginia and may be served through its registered agent: CT Corporation System, 5098 Washington St. W., Suite 407, Charleston, WV, 25313. At all times material herein, Express Scripts Sales Operations, Inc. was transacting business

in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities.

- 159. Collectively, Defendants Express Scripts, Inc.; Express Scripts Administrators, LLC; Medco Health Solutions, Inc.; ESI Mail Order Processing, Inc.; ESI Mail Pharmacy Service, Inc.; Express Scripts Pharmacy, Inc.; Express Scripts Specialty Distribution Services, Inc.; Express Scripts Sales Operations, Inc.; Evernorth Health, Inc. (formerly Express Scripts Holding Company); Evernorth Care Solutions, Inc.; Evernorth Direct Health, LLC; Evernorth Behavioral Health, Inc.; and Evernorth Sales Operations, Inc., including all predecessor and successor entities, are referred to as "Express Scripts" or "ESI."
- 160. Express Scripts is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, and research provider; and (3) mail order pharmacy. During the relevant time period, Express Scripts contracted directly with the opioid manufacturers in each of these capacities. At all relevant times, Express Scripts performed these services in West Virginia and Plaintiffs' Communities.
- 161. In 2019, Express Scripts merged with Cigna, Inc. Prior to merging with Cigna, Express Scripts was the largest independent PBM in the United States.
 - 162. In 2012, Express Scripts acquired Medco in a \$29.1 billion deal.
- 163. Prior to 2012, Express Scripts and Medco were separate companies. Standing alone, these companies were two of the largest PBMs in the country and had been since at least the mid-1990s.
- 164. As a result of the merger, the combined Express Scripts was formed and became the largest PBM in the nation.

- 165. Following the merger, all of Medco's PBM and data and research functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's clients becoming Express Scripts' clients and Medco's top executives becoming Express Scripts executives.
- 166. The chart represents the consolidation of PBM entities that that are now all part of Express Scripts today:



- 167. Express Scripts is now the largest PBM in the United States, with annual revenue (as of 2022) of over \$100 billion. Express Scripts provides pharmacy benefit service to more than 100 million Americans, filling 1.4 billion prescriptions per year.
- 168. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used by Express Scripts' clients nationwide, including in West Virginia, this Judicial District, and in Plaintiffs' Communities. Express Scripts' national formularies include its National Preferred Formulary, Basic Formulary, High Performance Formulary, and Prime Formulary. These Express Scripts formularies were utilized by prescription drug benefit plans in West Virginia and this Judicial District covering services and prescriptions in Plaintiffs' Communities throughout the relevant time period. At all times relevant hereto, those formularies dictated the terms of

reimbursement for opioids dispensed in West Virginia, this Judicial District, and Plaintiffs' Communities.

- 169. Express Scripts offers pharmacy benefit services to a variety of plan sponsors with covered lives in Plaintiffs' Communities, including both large national companies and local/regional businesses.
- 170. Express Scripts (and/or its predecessors) processed claims for prescription opioids dispensed pursuant to Express Scripts' national formularies and standard UM guidelines in Plaintiffs' Communities throughout the opioid epidemic.
- 171. At all times material herein, Express Scripts (and/or its predecessors) transacted business in West Virginia and its conduct had a direct effect in West Virginia, including in Plaintiffs' Communities. Upon information and belief, Express Scripts derived and continues to derive substantial revenue as a result of managing pharmacy benefits in this Judicial District and throughout West Virginia, including within Plaintiffs' Communities.

2. Agency and Authority

172. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Express Scripts' officers, agents, employees, or other representatives while actively engaged in the management of Express Scripts' affairs within the course and scope of their duties and employment, and/or with Express Scripts' actual, apparent, and/or ostensible authority.

IV. Express Scripts' Conduct Created an Abatable Public Nuisance in Each Plaintiff's Community.

173. As alleged throughout this Complaint, Express Scripts' conduct created a public health crisis and public nuisance in each Plaintiff's respective Community.

- 174. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Express Scripts can be abated and further recurrence of such harm and inconvenience can be abated by, inter alia, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; (c) making naloxone widely available so that overdoses are less frequently fatal; (d) developing and implementing evidence-based strategies, programming, and services used to expand the availability of treatment for individuals affected by substance use disorders and addiction; (e) developing, promoting, and providing evidence-based substance use prevention strategies; (f) providing substance use avoidance and awareness education; (g) engaging in enforcement to curtail the sale, distribution, and promotion or use of opioids and other drugs; (h) decreasing the oversupply of illicit opioids; and (i) supporting recovery from addiction performed by qualified providers.
- 175. Indeed, through its passage of W. Va. Code § 5-31-1, *et seq.*, the West Virginia legislature recognized that the opioid epidemic is abatable. *See* W.Va. Code § 5-30-1(c) ("The creation of a private foundation will advance the goal of abating the opioid epidemic by providing a long-term steady stream of money to fund the efforts by both private and governmental entities.")
- 176. Express Scripts has the ability to act to abate the public nuisance, and the law recognizes that it is uniquely well positioned to do so. Express Scripts along with others in the supply chain are primarily responsible for ensuring that prescription opioids are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any Food and Drug Administration ("FDA") or DEA regulation, to ensure that its services and

practices meet both federal and state laws and regulations. As a registrant and/or licensee, Express Scripts is placed in a position of special trust and responsibility and is uniquely positioned, based on its knowledge to act as a first line of defense.

V. The Role of PBMs Such As Express Scripts in Prescription Drug TransactionsA. PBMs Operate on All Sides of Prescription Drug Transactions.

PBMs such as Express Scripts contract with insurers, self-insured employers, and state and federal government agencies (referred to by the PBMs as their "clients") to provide pharmacy benefit management services. One of the services the PBMs provide is to create standard, national formularies and UM programs. The PBMs offer these standard formularies and UM programs to their clients, and most clients adopt these standard offerings for their prescription drug plans without modification. In crafting these standard formularies and UM programs, PBMs review and make determinations regarding which medications are effective or appropriate. PBMs also review and pay claims for the drugs dispensed to their covered lives. As a result, PBMs exert significant influence over prescriptions dispensed in the United States and in West Virginia, including influencing the quantity, dosage strength, duration, and refill availability for each prescription. PBMs also collect and maintain all of the data associated with all of the prescriptions dispensed to their covered lives, giving them granular insight into the ongoing health and pharmaceutical patterns of these patients. This data is available to the PBMs when they craft their standard formularies, implement standard UM programs and even informs standard "retrospective" utilization" programs that offer services to patients after a prescription has been filled.

178. Although PBMs contract with third-party payors to provide pharmacy benefit management services, they also contract with drug manufacturers and with pharmacies. They are paid by their clients to make safe and effective drug therapies available to their covered lives. But, as described below, they are also paid by drug manufacturers to provide the greatest access to their

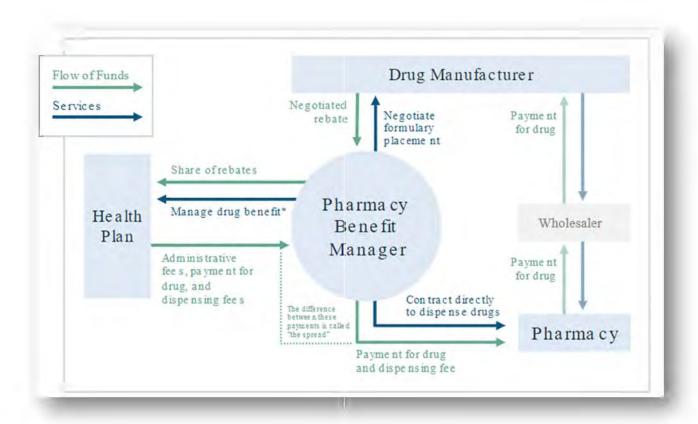
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products, so as to increase sales, with little to no regard for safety or efficacy. And they are paid by the pharmacies where the plan beneficiaries' prescriptions are filled, to verify coverage but also to assist the pharmacy in ensuring that a prescription is appropriate. Thus, in any given transaction, a PBM may be receiving money from both the payor and the pharmacy to exercise independent judgment about whether to authorize payment for a prescription, while also receiving money from the manufacturer to ensure that the sale is made.

- 179. The business model that PBMs, including Express Scripts, use is thus rife with conflicts of interest and self-dealing through which they have enriched themselves at the expense of their clients and the public. Inherent in the services offered by Express Scripts in its agreements with the opioid manufacturers (and with pharmacies) are the same services for which it has already ostensibly received payment from its clients, albeit with the incentives often running in the opposite direction.
- 180. This chart illustrates the central role PBMs like Express Scripts play in the prescription drug market:⁵

⁵ The Commonwealth Fund, *Pharmacy Benefit Managers and Their Role in Drug Spending* (Apr. 22, 2019),

https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.



- 181. It is in part because of the multiple roles that PBMs play in prescription drug transactions that they have access to, and collect, the vast amounts of data they have. No other party has access to so much data because no other party is so thoroughly embedded into every aspect of prescription drug prescribing and dispensing.
- 182. Yet rather than use their vast data resources to craft formulary and UM offerings that would address the dangers of opioids and help reduce utilization of these dangerous drugs, Express Scripts instead worked with opioid manufacturers to adopt policies and offerings that drove opioid utilization and helped fuel the epidemic. In pursuit of opioid profits, Express Scripts intentionally disregarded its obligations, to the detriment of communities around the country, including Plaintiffs' Communities.

B. PBMs Use Their Formularies as Leverage to Negotiate with Drug Manufacturers.

- 183. Formularies are a central tool that PBMs, including Express Scripts, offer to clients for use in designing, managing and publicly identifying the extent of the coverage and benefits provided to their covered lives. Because formulary listing affects how much a patient pays for a drug, formulary placement makes a prescriber more likely to prescribe, and a patient more likely to pay for, certain drugs over others. Indeed, driving drug utilization is one of the key purposes and functions of formulary design, implementation, and management.
- 184. Moreover, the PBMs' clients rely upon Express Scripts' formularies. The Pharmaceutical Care Management Association ("PCMA"), the PBM trade association, testified to the Pennsylvania House of Representatives that even sophisticated clients rely almost entirely on PBMs to manage their drug benefit. Indeed, it is their expertise that the PBMs are marketing to their clients, so it makes sense that most clients rely on that expertise and, lacking their own expertise, have little choice but to do so. Many PBM clients utilize the PBMs' standard national formularies. Even though there may be a few large, sophisticated clients that ostensibly use "custom" formularies, in reality, these formularies often either mirror the PBMs' standard formularies or were constructed in large part by the PBMs.
- 185. Since Express Scripts' standard formulary offerings heavily influence drug reimbursement terms for 160+ million covered lives, Express Scripts has significant leverage when negotiating with brand drug manufacturers. Express Scripts uses this leverage to maximize the amount of rebates paid to it by brand drug manufacturers, including opioid manufacturers. These rebates are paid to Express Scripts on every eligible drug dispensed; thus, the more Express Scripts drive utilization, the more rebates are paid by opioid manufacturers to it.
- 186. Rebate eligibility is a critical factor. In a typical PBM rebate contract with an opioid manufacturer, eligibility for rebate payments is tied to the way a particular drug is treated on the

formulary and whether the drug is or is not "restricted" by UM. Put differently, if a drug is placed on a non-preferred tier, or if the drug is restricted by UM programs, rebates will either be adversely impacted or not paid at all.

- 187. Thus, Express Scripts is incentivized to structure its standard formulary and UM offerings in ways that enhance and do not restrict opioid utilization so that it can maximize the rebate payments for which it will be eligible.
- 188. PBMs do at times share manufacturer rebates with their clients. But Express Scripts generally passes through only a portion of these rebates to its clients and retain the rest as profit. As a result, Express Scripts has profited handsomely from rebates received from drug makers, including opioid manufacturers, for each brand drug sold.
- 189. In addition, if a PBM can generate higher volume (more sales) for manufacturers, it can then negotiate higher rebates that the manufacturer will pay to the PBM (which in turn increases the PBMs' profit).
- 190. PBMs also make profits in other ways by increasing the volume of prescriptions that are sold to their covered lives. One way is through money that the PBMs earn on "spread pricing." Spread pricing is where a PBM will charge its client a higher price for a prescription than what the PBM pays the pharmacy for the same drug. The PBM will then pocket the difference in this price spread as profit. Spread pricing is particularly profitable for the PBMs for generic drugs, including generic opioids. Put simply, the more generic opioid prescriptions dispensed to the PBMs' covered lives, the higher profit the PBM earns through this spread pricing.
- 191. Ultimately, PBMs are very much incentivized to keep sales volumes high for both generic and brand opioids.

- 192. As a result, PBMs—including Express Scripts—have a monetary interest in ensuring that favored drugs are covered, prescribed, and dispensed.
- 193. The structure of the pharmacy benefit market also aids Express Scripts' efforts to maximize opioid manufacturer rebates. Express Scripts became a major force in the late 1980s, expanding from solely processing pharmacy claims to a business model that invited drug manufacturers to negotiate prices in several drug categories. Because of market consolidation, Express Scripts controls a significant portion of the pharmacy benefit market. The PBM market is thus highly concentrated, both within West Virginia and throughout the United States.
- 194. In contrast, the market for their clients is much less concentrated, with the largest companies accounting for less than two-thirds of the business in 2014. For brand-name drug manufacturers, thirteen companies account for 90% of the U.S. pharmaceutical market. Thus, it is typical to have one of the (large) PBMs negotiating with the (large) opioid manufacturers on behalf of a number of relatively small clients.
- 195. The small world consisting of Express Scripts and approximately ten opioid manufacturers facilitated collusive negotiations that benefitted the manufacturers and Express Scripts at the expense of patient health and safety. For example, PBMs have typically used their clout to negotiate master rebate agreements on behalf of all their covered lives. Rather than negotiate with respect to, or on behalf of, particular clients or particular plans, they enter into master agreements that will apply across the board. As a result, in the world of drug price negotiation, market power is most highly concentrated among PBMs like Express Scripts, who have more negotiating leverage than any individual drug manufacturer or health plan on either side of a transaction.

196. These negotiations can be of such great financial importance to pharmaceutical companies and PBMs like Express Scripts that they are often attended by senior executives up to and including the chief executives, which has also facilitated the formation of personal business relationships and an understanding of the common purpose of the negotiations between Express Scripts and the prescription opioid manufacturers.

197. Because Express Scripts is paid based on the volume of prescriptions, including for opioids, that flow through their formularies, restricting this flow would cause Express Scripts to lose substantial revenue.

198. Moreover, rebate payments are only part of the payments Express Scripts receives from opioid manufacturers. In addition to rebates, drug manufacturers, including opioid manufacturers, have paid Express Scripts substantial amounts of various "administrative fees" and "service fees" in exchange for, among other things, ensuring a given drug's formulary placement and providing various services to the drug makers—the same services they are already being paid to provide to their clients.

199. For example, Express Scripts' standard form of contract discloses that it receives "administrative fees" for, among other things, providing opioid manufacturers access to "drug utilization data, and receives "service fees" (which are explicitly described as separate from both rebates and administrative fees) for "formulary compliance initiatives, clinical services, therapy managements services, education services, medical benefit management services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information":

ESI provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and

operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.⁶

- 200. Express Scripts is able to minimize the portion of money from drug manufacturers that it passes along to its clients in part through misleading labeling of the various payments. This lack of transparency, and Express Scripts' central role in ensuring it, has allowed Express Scripts to conceal its collusion with the opioid manufacturers from their own clients and from the public.
- As industry expert Linda Cahn observed, "[i]f a PBM enters into contracts with 201. drug manufacturers and chooses to give rebates another name—like administrative fees or health management fees or grants—the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients."⁷
- 202. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to pharmacy-benefits consultant David Dross, administrative fees can amount to 25-30% of total payments from drug companies like Purdue.

⁶ ESI_JEFFCOMO_000231588 (1/1/14).

⁷ Jeanne Pinder, "Don't Get Trapped By PBM's Rebate Labeling Games: Managed Care Clearmagazine Linda Cahn" HealthCosts(Feb. 26, 2018), by https://clearhealthcosts.com/blog/2018/02/dont-get-trapped-pbms-rebate-labeling-gamesmanaged-care-magazine/.

1. Express Scripts' Formularies

203. Express Scripts develops operative national formularies utilizing three committees—Therapeutic Assessment Committee ("TAC"), Pharmacy & Therapeutics Committee ("P&T"), and the Value Assessment Committee ("VAC"). The TAC reviews the clinical properties of new drugs and pre-existing drugs (to the extent new or developing clinical information warranted such review) and prepares research memoranda discussing the benefits and drawbacks for each drug. The TAC also makes recommendations regarding whether any particular drug under review should or should not be included on Express Scripts' national formularies. The TAC's research memoranda and recommendations are then provided to the Express Scripts' P&T Committee.

204. The P&T Committee consists of outside, third-party medical providers who were not employees of Express Scripts. Express Scripts claims that the P&T is fully independent and exercises its own clinical judgment. Express Scripts further claims that "the P&T Committee considers the drug's *safety and efficacy*," and the company "fully compl[ies] with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of *safety and efficacy*."

205. The P&T reviews the research memoranda provided by TAC. The P&T then places each drug it reviewed into one of three categories: "must include," which meant that the drug must be included on Express Scripts' national formularies; "must exclude," which meant the drug could not be included on Express Scripts' national formularies; and "optional," which meant that the drug could or could not be included on national formularies, at the discretion of yet a third committee.

⁸ *Id.* (emphasis added).

206. This third committee is known as the VAC. Like the TAC, the VAC also consists of Express Scripts employees. But, in important other respects, the VAC is different. Notably, while Express Scripts represents that neither the TAC nor the P&T is supposed to consider any financial or economic factors, the VAC expressly considers financial factors. The financial factors considered by the VAC include rebates and administrative fees paid by manufacturers, including the opioid manufacturers. At all times Express Scripts has benefited from these rebates and administrative fees because Express Scripts retains some portion of them. After considering these financial factors, the VAC is then the committee that actually constructs the Express Scripts' national formularies, and determines on which tier a drug is placed. The lower the tier, the greater the access/utilization.

C. Express Scripts' Drug UM Programs

- 207. In connection with their formulary development, Express Scripts also creates standard drug UM programs and rules, which it offers to its clients and which most clients adopt.
- 208. One example of UM offered by Express Scripts since at least the late 1990s is a "quantity limit," or QL, which is a utilization management tool that limits the total dosage of a particular drug that a beneficiary may receive. Another example is a "step edit" or "step therapy," which requires a patient to try a different drug (designated by the PBM) before the patient can receive the drug they were prescribed. Another is a "prior authorization," or PA, which is a tool that requires a clinical follow-up with the prescribing physician prior to the drug being dispensed to double-check and make sure the prescription is appropriate for the patient beneficiary.
- 209. Studies, including those conducted by Express Scripts itself, have shown that implementing PAs can reduce the utilization of dangerous and addictive drugs like OxyContin. Thus, like its standard formulary offerings, standard UM offerings are another tool Express Scripts

uses to steer patients. UM tools, if used as intended, should act as an impediment to patients gaining access to drugs that are susceptible to oversupply and abuse, or that are more costly than others.

- 210. Express Scripts' business is based on a model of standardization. While clients have the option to design their own programs, most clients accept the standard formularies and UM programs, like step therapy, prior authorizations and drug utilization review ("DUR") edits. Thus, it is the manner in which Express Scripts construct their standard formularies and programs (outside of any client interaction) that has an enormous influence on drug utilization.
- 211. The amount of influence that Express Scripts has over drug utilization was a frequent topic of discussion between Express Scripts and the opioid manufacturers that was central in the parties' discussions about rebates and administrative fees. The more Express Scripts could drive market share to or away from a drug by controlling formulary and UM decisions, the more an opioid manufacturer was willing to pay.
- 212. Notably, Express Scripts leverages its ability to steer drug utilization to generate substantial profits. Indeed, Express Scripts profits from every branded and generic opioid sold in myriad ways.
- 213. Express Scripts has always had the ability to provide baseline opioid UM controls for its clients, which it did on September 1, 2017 (when Express Scripts offered its Advanced Opioid Management program) and January 1, 2018 (when it kicked off their Opioid Risk Management Program).

D. Express Scripts' Contracts with Pharmacies

- 214. As noted above, PBMs, including Express Scripts, also contract directly with retail pharmacies to dispense drugs to a patient.
- 215. Express Scripts contracts with approximately 65,000 retail pharmacies, representing over 98% of all retail pharmacies in the United States, including, upon information

and belief, pharmacies in West Virginia, this District, and Plaintiffs' Communities. These pharmacies become part of Express Scripts' network for coverage purposes.

216. When a pharmacy is in the network with Express Scripts, a covered patient pays out-of-pocket for a small portion of the prescription and the PBM arranges for direct payment to the pharmacy of the remainder of the cost of the prescription. In this way, covered patients need not advance the cost of their prescriptions and seek reimbursement afterwards.

217. In connection with contractual arrangements with their network pharmacies, the PBM determines the patient's copay and how much it will reimburse pharmacies for each medication covered under the drug plan. PBMs generally pre-determine how much each drug covered under their standard formularies should cost, and this determination affects the amount they reimburse to the pharmacies. Critically, Express Scripts also receives real-time claims data from pharmacies at the point of sale, as part of their electronic adjudication of claims, which includes determining eligibility for reimbursement and conducting concurrent drug utilization review ("cDUR," discussed in detail below).

218. As described below, pursuant to its contracts with its network of pharmacies, Express Scripts undertakes to perform "drug utilization review" and to provide mechanisms to ensure safe dispensing. Express Scripts claims that it uses drug utilization review to "review prescriptions for safety and effectiveness, in real-time, electronically and systematically, when presented to our pharmacies or submitted for coverage by network pharmacies, and alert the dispensing pharmacy to detected issues. Issues not adequately addressed at the time of dispensing may also be communicated to the prescriber retrospectively."

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⁹ *Id*.

- VI. Express Scripts' Role in Causing the Opioid Epidemic and Public Nuisance in Each Plaintiff's Respective Community.
 - A. Express Scripts and the Prescription Opioid Manufacturers Colluded to Ensure Virtually Unfettered Access to Prescription Opioids.
 - 1. Express Scripts Negotiated with the Prescription Opioid Manufacturers to Give Prescription Opioids Favorable Placement on National Formularies in Exchange for Rebates and Other Fees.
- 219. As noted above, PBMs like Express Scripts have significantly more market power than the drug manufacturers with whom they negotiate drugs prices and formulary placement. The vast market power of Express Scripts compared to its clients has allowed it to negotiate deals with the opioid manufacturers for the payment of additional rebates and other fees that the opioid manufacturers pay to Express Scripts that induced the cooperation of Express Scripts and the prescription opioid manufacturers to work together in a fraudulent scheme.
- 220. The terms of the agreements between opioid manufacturers and Express Scripts are considered extremely confidential by Express Scripts and are not even disclosed to their health plan clients. As a result, until key highly confidential documents were recently obtained in discovery in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804-DAP (N.D. Ohio), and other opioids litigation, there has been little public insight into how these agreements affected the volume of opioids flooding American households.
- 221. From the time it first released OxyContin, Purdue pushed its sales force to "Sell, Sell OxyContin."¹⁰ In an early sales memo in 1996, Purdue's head of sales stressed that his team should "[r]emain focused on positioning OxyContin as the opioid to start with and stay with in chronic malignant and non-malignant pain states. In addition, continue to aggressively position

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¹⁰ PDD1503490547.

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OxyContin for use in osteoarthritis, low back pain, post neuropathic neuralgia and post-surgical applications."11

- 222. Purdue's aggressive marketing campaign worked and OxyContin sales exploded in the years following its release, reaching almost \$2 billion in annual sales by 2003. In addition, during this same time period the annual number of OxyContin prescriptions for noncancer pain increased nearly tenfold, from about 670,000 in 1997 to about 6.2 million in 2002.
- 223. During this time of rapidly expanding OxyContin sales, Medco was the largest customer of Purdue products. For example, in 1996, Medco was the largest PBM in the country and received over one-third of the rebates paid by Purdue for all opioid sales. By 2001 and 2002, Medco's gross sales of Purdue opioids totaled \$250.4 million and \$281 million respectively, "making [Medco Purdue's] largest customer." 12
- 224. When OxyContin was first released, Medco made several attempts to restrict its utilization. For example, in early 1996, Medco established a "ceiling dose" quantity limit for OxyContin of 80 mgs/day because of the potential for abuse for that drug. 13
- 225. In January 1997, Purdue received notice from "pain clinic doctors" that Medco was sending letters to prescribers because of a "concern[] about abuse potential" in patients taking OxyContin for chronic non-malignant pain. 14 Medco's concerns were forwarded up to several high ranking Purdue executives, including the president of the company, Richard Sackler. 15 James Lang, head of marketing and sales at Purdue, explained, "Our success with OxyContin is starting

¹¹ *Id*.

¹² PPLPC012000064369.

¹³ PDD1715057333.

¹⁴ E513 00045035.

¹⁵ E513 00006452; E513 00045035; PDD9316506319.

to create concerns amongst the large PBMs as you already know because they recognize we are targeting non cancer pain. This goes beyond their initial perception that [OxyContin] was primarily a cancer pain medication."¹⁶

- 226. While this issue was originally presented as a concern about addiction and abuse, a number of Purdue executives saw this as pretextual, and thought that Medco's true intentions were focused on cost and extracting larger rebates.
- 227. For example, when Purdue's medical director Paul Goldenheim suggested, "[w]e need to talk to Medco and others about addiction," Purdue's president Richard Sackler responded, "we should consider that 'addiction' may be a convenient way to 'just say 'NO' and when this objection is obliterated, [Medco] will fall back on the question of cost." 17
- 228. Mark Alfonso, Purdue's vice-president of marketing, also weighed in: "My impression of this issues is that there are several major products . . . that are growing at a great rate and [managed health care]¹⁸ organizations are not slowing them. . . I also believe that a lot of what [Purdue's Managed Care Account Executives] hear from their accounts is with the intention of softening them up before the [managed health care] asks for more aggressive rebates. They are told 'I am going to drop you from the formulary' for several months and then one day they are told if you give me higher rebate you can keep OxyContin in the formulary." ¹⁹
- 229. Purdue executives did, however, recognize the substantial threat this posed to OxyContin's success—if Purdue did not take immediate action to address Medco's economic concerns it could be an existential threat to Purdue's business. Sales and marketing executive

 $^{^{16}}$ *Id*.

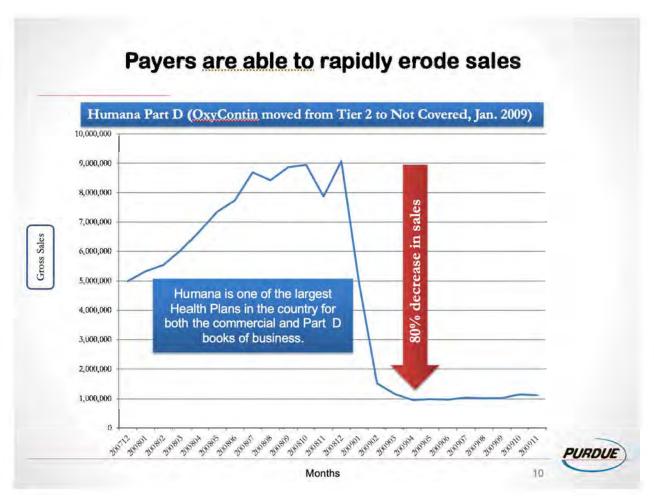
 $^{^{17}}$ *Id*.

 $^{^{\}rm 18}$ Purdue refers to payors, such as Express Scripts, as "managed care."

¹⁹ E513_00006452.

Michael Friedman (who would later become Purdue's CEO), stated, "If we do not do [demonstrate the economic value of OxyContin], I can promise you that we will eventually be shut out. . . This is a serious matter that we cannot ignore and that we must discuss . . . We cannot go on ignoring the reality of [the PBMs'] economic proof requirements . . . If we are to stay in business we need this proof of economic performance."²⁰

Purdue's own data shows the impact that a major payor (such as Medco) moving 230. OxyContin from a preferred formulary tier to an excluded product has on utilization:²¹



²⁰ E513 00045035.

²¹ PPLPC030000773368.

231. Ultimately, in response to Medco's actions in 1996, Purdue determined that it needed to expand the OxyContin market by demonstrating the economic value of OxyContin in chronic non-cancer pain use to Medco and other PBMs. As Paul Goldenheim, Purdue's medical director, explained to Richard Sackler: "We have the tiger by the tail, and I wonder if we should add more muscle. Let's discuss over live sushi!" 22

- 232. Importantly, had Medco in 1997—Purdue's largest customer at that time—excluded OxyContin from its formularies or put in place hard UM edits (i.e., prior authorizations) to restrict OxyContin use in non-cancer pain treatment it would have had a substantial impact on the success of OxyContin and would possibly have driven the drug off the market. Other major payors at that time, such as Cigna, had excluded OxyContin from their formularies.
- 233. Medco, however, did not take action to exclude or restrict the sales of OxyContin. To the contrary, within three months of this exchange between Purdue executives, as detailed in this May 1997 Purdue memo, Medco had completely reversed course and "become very interested in 'partnering with Purdue'" on numerous projects to expand opioid use into the chronic pain market:²³

²² E513_00045035.

²³ PPLPC025000003668.

Managed Care

To: Jim Lang
Ernie Merlino

From: Tim Richards

Subject: Medco

of

Date: May 4, 1997

Per our discussion on Medco on Friday, May 2, 1997 the following is a summary of information that has surfaced since the meeting with Medco in August, 1996.

- Along with Isaac Schulman, Mel Grayson has been calling on Joe DaBronzo, Pharm.D., who was promoted to Director of Utilization Management at Medco. Mr. DaBronzo feels that Medco's network is not properly trained on the basics of assessment and management of pain. It was Mr. Dabronzo's and Mr. Schulman's opinion that internally, Medco health care professionals needed education on pain assessment and management. Mel has set up a speaker program with Dr. Elizabeth Narcessian at Medco for May 13, 1997.
- Pertaining to discussions at the August, 1996 meeting at Medco and accentuated by Mr. DaBronzo's recent promotion, decision makers at Medco have become very interested in "partnering with Purdue" on pain assessment and management. Mr. DaBronzo is interested in developing the following materials with the help of Purdue:
 - Medco specific pain protocols for not only cancer pain, but for chronic non-malignant pain.
 - Purdue to initiate retrospective outcome pharmacoeconomic studies using and partnering with Medco data.
 - Purdue's consideration of Medco intervention for Purdue products and a negotiation market share/performance-based contracts from this intervention.
 - Education materials (CME disease state related) for physicians, case workers, nurses and pharmacists in the Medco system.
 - Disease related patient education on pain assessment and chronic pain patient care.

With the above list, and the scheduled speaker program, Medco would like to move forward with Purdue in partnering for pain management into the future. Medco has requested of Mel Grayson for Purdue to move forward quickly in deciding whether Medco's partnering ideas are of any interest.

- 234. Notably, within three years of this memo, Joe DaBronzo, Medco's Director of Utilization Management, took a position as an executive director at Purdue.
- 235. As a first step reflecting its new "partnership" with Purdue, Medco significantly raised its quantity limits on OxyContin. As discussed above, Medco initially implemented an 80 mg/day quantity limit at the release of OxyContin. However, within five months of the release and

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following further discussions with Purdue, Medco doubled it to 160 mg/day by May 1996. And by at least 2001, Medco again doubled this quantity limit and the "most restrictive [quantity limit] that Medco would recommend is for 320mg/day as per [Purdue's] platform."²⁴ For comparison, Express Scripts' current Advance Opioid Program has a 90 MME/day opioid quantity limit for opioid naïve patients. Medco's 320mg/day is equivalent to 480 MME/day—over four times the limit that Medco originally placed on OxyContin upon its release, as well as over *five times* the limit that Express Scripts now imposes on the drug.

- This covert collusion between Express Scripts and the opioid manufacturers opened 236. the flood gates to the unfettered formulary access for their opioids in exchange for rebates and other fees.
- 237. Express Scripts' influence over formulary positioning has been a key contributor to the ongoing relationship with the opioid manufacturers because the manufacturers pay rebates and other fees based on Express Scripts' ability to deliver favorable drug placement within their standard formulary offerings. Because favorable formulary status is likely to increase a drug's usage and sales, and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug's usage and sales, the rebates and other fees are conditioned on a drug's formulary status. As Cottingham & Butler (a national insurance broker) noted in a client presentation, PBMs have "unilateral control . . . over formularies and tiering—driving greater profits for PBMs through rebates[.]"25

²⁴ PPLPC012000064369.

²⁵ Nancy Daas, "Prescription Drug Plan Strategies," Cottingham & Butler (Mar. 2017) https://www.cottinghambutler.com/wp-content/uploads/2017/03/Prescription-Drug-Strategies.pdf.

- 238. Express Scripts and the opioid manufacturers regularly discussed and agreed about which, if any, UM measures would be utilized for particular opioid drugs.
- 239. As discussed above, Express Scripts maintains internal committees that determine which drugs are placed on its formularies. These committees are comprised of company personnel. In addition, Express Scripts has trade relations employees who are responsible for negotiating rebate agreements with drug manufacturers. Express Scripts refers to this committee as the Trade Relations Group.
- 240. Years ago, the PBMs devised and managed what were known as "open" formularies: formularies that offered varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies strived to have their drugs placed by PBMs on the portion of the formulary that allowed the easiest (and least expensive) access to their drugs.
- 241. By the 2000s, however, Express Scripts began shifting to "closed" formularies as the standard offerings to their clients. "Closed" formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs that are on the formulary. For the past two decades, most PBM covered lives have been governed by closed formularies.
- 242. As noted above, Express Scripts has greatly influenced access to opioids through formulary placement. Preferential formulary placement, such as being listed on a lower cost tier, increases a drug's utilization. Additionally, Express Scripts has influenced access to opioids through UM measures they utilize (or elect not to utilize) as part of their standard formularies. When implemented properly, UM measures could have restricted much of the flow of opioids entering the market.

243. Since at least 2000, prescription opioid manufacturers have paid rebates and other fees to Express Scripts in exchange for preferred formulary placement for their opioid products.

244. The prescription opioid manufacturers early on recognized that Express Scripts would provide unrestricted formulary status on its standard formularies in exchange for rebates and other fees. For example, in a candid February 15, 2000 email exchange, Purdue Managed Care Account Executive David Wallen explained that he could get Express Scripts "to steer [OxyContin] prescriptions" to retail pharmacies because of the rebates it received. ²⁶ According to Wallen, "Express Scripts makes their money from the rebate, so they cannot make any money on this account if they do not get rebates." In a later February 25, 2000 email, Wallen explained that Express Scripts pressured its clients to put OxyContin on its formularies without restrictions: "[Express Scripts puts] pressure on [their client] to put OxyContin on formulary . . . because they make their money from rebates, and they do not get rebates if OxyContin is [subject to UM restrictions that reduce prescriptions]." ²⁸

245. For almost every year since 2001, Express Scripts and Medco granted OxyContin preferred formulary placement in its standard, national formularies.

246. Internal Express Scripts documents show that by 2013, some within Express Scripts believed that, with respect to OxyContin, Express Scripts was "out of alignment with the rest of the PBM/Health Plans in . . . putting this drug on a preferred tier (and) that other organizations have leaned more towards taking a harder stance on this highly abused medication."²⁹

²⁶ PPLPC024000012498 (2/28/00).

²⁷ *Id*.

 $^{^{28}}$ *Id*.

²⁹ ESI_JEFFCOMO_000265250 (4/19/13).

247. By the time of the Express Scripts-Medco merger, internal Purdue meeting notes reflect that in a meeting between Express Scripts/Medco and Purdue, Express Scripts/Medco representatives stated that "when Medco reviewed the drug spend for 2013, OxyContin was at the top of the list . . . OxyContin use at Medco is out of control compared with [the other large PBMs] Patients are selecting Medco because Medco [has] OxyContin in a preferred position."³⁰

248. After the merger (and years after it knew OxyContin was a heavily abused drug), Express Scripts was still pushing Purdue for more rebate dollars in exchange for granting OxyContin preferred positions on its standard formularies. In 2014, Express Scripts reached out to Purdue requesting a higher rebate rate for OxyContin to maintain its preferred position. Purdue executives agreed given the importance of the Express Scripts relationship to OxyContin sales, stating: "[Express Scripts/Medco commercial is 20-25% of our total OxyContin gross business, and the spillover effect of a negative move by [Express Scripts] on OxyContin in 2015 cannot be underestimated . . . Given the importance and impact of this customer on OxyContin sales . . . I approve [the decision to increase OxyContin rebate rates]." Express Scripts celebrated this rebate increase as a win: "we got \$20M in incremental from Purdue on OxyContin . . . Not too bad considering likely not doing anything."

249. Notably at the same time (2014) that Express Scripts was pushing Purdue for more rebates to continue preferring OxyContin on its formularies, Express Scripts was also preparing the press releases and sales communications for its "Nation in Pain" report (discussed above).³² Thus, on one hand Express Scripts was releasing a report for marketing purposes on the opioid

³⁰ PPLPC012000373022.

³¹ PPLPC012000475266; PPLPC035000217128; Zilocchi Dep. Ex. 13.

³² Nowak Dep. Ex. 10.

epidemic in 2014 to "highlight the power of Express Scripts data and clinical expertise, and our commitment to identifying ways to make the use of prescription opiates safer and more effective," while on the other hand Express Scripts was receiving millions of dollars in extra rebates in order to continue to preferring the drug that started the opioid epidemic (OxyContin) on its standard formularies.

- 250. Despite its knowledge of the nationwide opioid health crisis, and despite its knowledge of the impact that preferred formulary placement and the lack of UM restrictions had on increasing opioid sales, through at least 2017, Express Scripts continued granting OxyContin on the most preferred brand formulary tier, with no UM restrictions, on nearly all Express Scripts' standard formulary offerings.
- 251. Express Scripts has been so successful in working with the opioid manufacturers to optimize their common purpose between formulary placement/utilization management and rebates and other fees that payments have reached as high as 70% to 80% off wholesale acquisition cost for some opioid drugs.
- 252. To make matters worse, as the market shifted from branded opioids to generics in the mid-2000s, Express Scripts continued to grant generic opioids unrestricted and preferred placement on its standard formularies because of the profits these drugs generated for Express Scripts through spread pricing and in other ways.
- 253. Thus, from the late 1990s through 2018, Express Scripts and Medco granted both brand and generic opioids, including OxyContin, preferred positions on its standard formulary offerings, which was critical to the success of the opioid manufacturers increasing utilization and expanding the opioid market nationally, in West Virginia, in this District, and in Plaintiffs' Communities.

- 2. Express Scripts and the Prescription Opioid Manufacturers Used Parity to Limit the Use of Utilization Management Measures for Prescription Opioids.
- 254. If they had been implemented earlier, Express Scripts' UM measures would have helped control the flow of opioid drugs into every community in America, including Plaintiffs' Communities. These measures include days' supply quantity and daily dosage limits, refill-toosoon limits, prior authorizations (which require additional approval before drug is dispensed) and step edits (which could require that a patient try a different, safer drug before being given a more dangerous one).
- 255. Express Scripts, however, has financial incentives to give opioids preferential treatment relative to other methods of treating pain (including non-pharmacological methods), and these incentives have made it less likely to mitigate inappropriate opioid usage. While Express Scripts has represented it uses UM measures to ensure only the safe and effective use of pharmaceuticals, behind closed doors it entered into confidential agreements with the opioid manufacturers to bargain away the use of these measures which would have limited dispensing to only medically appropriate uses.
- 256. Instead of placing limits on the inappropriate use of these dangerous drugs, Express Scripts bartered the use of UM measures which would have helped control the widespread abuse and diversion of opioids in Plaintiffs' Communities and in communities throughout the country.
- 257. Throughout their confidential negotiations with the opioid manufacturers, in exchange for rebates and other fees, Express Scripts agreed it would not "disadvantage" their opioid drugs, nor would they place UM restrictions on their use within their standard offerings. Effectively, this has meant that Express Scripts bartered away application of UM measures, which opened the floodgates to these dangerous drugs. Thus, the parties agreed that none of the opioid drugs would be disadvantaged and that they all would have the same UM restrictions as other

drugs that did not have the propensity for abuse inherent in opioid drugs. These parity and "no disadvantage" contract terms had the effect of Express Scripts and the opioid manufacturers sharing a common purpose of ensuring the unfettered access to opioids across the entire class of opioid drugs.

- 258. Express Scripts' standard rebate agreements defined the term "disadvantage" as any time when the opioid manufacturer's product is "subject to prior authorization, NDC blocks, counter-detailing, co-pay differentials, or a step edit that negatively had to have affects the reimbursement and/or Formulary status of the Product as compared to other products in its designated [competitive product category]..."
- 259. Express Scripts and Purdue's 2002 contract included language stating Purdue would not pay rebates if its opioids were restricted. Likewise in 2009, Purdue would only pay rebates if its opioids were "unrestricted on the preferred brand tier." Again in 2014, Purdue would only pay rebates on OxyContin if it was on "lowest preferred brand tier, without restrictions, including no prior authorization or step therapy." Even as late as 2016, Express Scripts acknowledged that if it tried to put any restrictions on OxyContin (such as restricting opioid use to acute pain, blocking opioids unless the use was for cancer or other approved uses, or requiring prior authorization) that it would violate its rebate agreements with Purdue and would result in a loss of rebates.
- 260. Another example occurred in 2010. During negotiations between Janssen and Medco (Express Scripts' predecessor) regarding the formulary placement of the fentanyl drug Nucynta, the parties agreed Janssen would only pay rebates so long there were no step edit

³³ ESI_JEFFCOMO_000250248 (1/1/16).

restrictions and agreed that Nucynta would be protected from "being disadvantaged vs. any branded agent in our defined market basket" of short-acting opioid ("SAOs").³⁴

- 261. Likewise, in 2012 negotiations between Express Scripts and Endo the parties agreed that "Endo Products are 'not disadvantaged to any other brand name pharmaceutical product in the same [competitive product category]" and that this disadvantaged language meant any UM restrictions must apply to all products in the competitive class.³⁵
- 262. The lockstep parity terms that Express Scripts and opioid manufacturers negotiated served and furthered the common purpose of the Formulary & UM Enterprise (described in greater detail below) because it normalized the use of UM measures across the entire class of opioids and guaranteed that the overall market for prescription opioids would not diminish because of utilization management. The rebate agreements conditioned payment on each opioid manufacturer not being disadvantaged with regard to applying UM measures unless the entire market basket of all competing drugs was treated the same. The parity terms therefore ensured that no single opioid manufacturer would be disadvantaged against the other and then, each could be free to compete outside of the Formulary & UM Enterprise for market share of their drug within the fraudulently increased system. The opioid manufacturers knew that UM presented a slippery slope—if more UM were employed, it would ultimately lead to the adoption of restrictions across the entire class of drugs.
- 263. Indeed, this is precisely what happened. As summarized in a 2017 Express Scripts document, "Opioid management is currently a hot button issue. Express Scripts clients are demanding a solution as CMS and states implement requirements around appropriate opioid

³⁴ JAN-NYDFS-00001455181 (2/25/10).

³⁵ ENDO-OPIOID MDL-07228036 (4/22/10).

management (i.e., 3 states took action on prescriber 1st fill day supply restrictions; 12 additional states in process of implementing restrictions around morphine equivalent dose edits etc.) . . . We anticipate our opioid retail margin to be at risk over the next two to five years as states and federal government continue to intervene and prescribing practices change."³⁶ This was obviously a significant issue to Express Scripts, which made roughly \$60 million in margin on opioids in 2016.

- 264. As alleged more fully herein, each member of the Formulary & UM Enterprise thus conducted and participated in the conduct of their enterprise through a pattern of racketeering activity—including mail and wire fraud—in which they formed a common purpose of growing the unfettered use of opioid drugs.
 - 3. Express Scripts Misrepresented It Was Using Its Formularies to Promote Safe Use and Appropriate Prescribing of Opioids.
- 265. Rather than provide transparency into their dealings with the opioid manufacturers, Express Scripts represented to its clients, patients, and the public that it used its market power to design formulary offerings to promote the safe use and appropriate prescribing of opioids. These representations were false. Express Scripts instead constructed standard formularies that garnered significant rebates and other fees in exchange for often unfettered access for "preferred" opioids.
- 266. For years, Express Scripts represented it promoted better health and was dedicated to making the use of prescription drugs safer. For example:
 - (a) For years between 2000 and 2010, Express Scripts represented in SEC filings that it "works with clients, manufacturers, pharmacists and physicians to . . . improve members' health outcomes and satisfaction."
 - During these same years, Express Scripts also represented in SEC filings that it "is a company dedicated to making the use of prescription drugs safer and more affordable for plan sponsors and over 50 million members and their families."

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³⁶ ESI_JEFFCOMO_000029922 (3/9/17).

- (b) During the same time period Medco represented in SEC filings that "[Medco] capitalize[s] on our clinical expertise and advanced information technology infrastructure . . . to improve safety and the quality of care for patients. We do this by developing action-oriented clinical programs and services based on clinical rationale..."
- (c) In its 2008 annual report, Medco represented that "[a]t Medco innovation, precision, and advocacy are in our DNA. We strive to make all of medicine smarter and as a result make healthcare better."
- (d) In a 2013 interview, Express Scripts CIO Gary Wimberly represented that "by filling 1.4 billion prescriptions per year, we have over 10 petabytes of useful data from which we can gain insights and for which we can develop solutions . . . [to] improve the health of patients." In addition, Mr. Wimberly stated, "[Express Scripts] has researchers and scientists whose sole job is to interpret and analyze the data to identify opportunities to improve health outcomes."
- Similarly, in a September 2013 letter to the Pennsylvania House of Representatives 267. Committee on Health, Express Scripts stated that "[o]ur company's mission is to make prescription drugs safer . . . "37
- In a 2013 interview, Express Scripts CIO Gary Wimberly summed it up: 268. "Everything we do every day focuses on health outcomes."
- As alleged more fully herein, despite Express Scripts' acknowledgement that it is 269. supposed to construct formulary and UM offerings that promote safe and affordable drugs for their members, Express Scripts has not actually done so. To the contrary, Express Scripts used its power to negotiate rebates and other fees, to control the offered formulary structures, to refrain from implementing or offering UM measures, all in an effort to allow the opioid manufacturers unfettered access to their formularies so that the number of opioids prescribed and sold could

³⁷ Letter from David Dederichs, Sr. Dir. Express Scripts to Matthew Baker, Pennsylvania House of Representatives, Comm. on Health, Re Opposition to HB 746, at 1 (Sep. 4, 2013) https://www.legis.state.pa.us/WU01/LI/TR/Transcripts/2013_0159_0011_TSTMNY.pdf.

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continue to grow and generate more profits for Express Scripts and the opioid manufacturers, thereby bringing the opioid epidemic to the doorstep of nearly every household in America.

- B. During the Early Years of the Epidemic, Express Scripts Conspired with the Prescription Opioid Manufacturers to Expand the Opioid Market and Increase Prescription Opioid Utilization.
- 1. Express Scripts Conspired with the Prescription Opioid Manufacturers to Increase Prescription Opioid Prescribing and Accepted Quid Pro Quo Payments in the Form of "Rebates" in Exchange for Increasing and Expanding Access to Prescription Opioids and the Prescription Opioid Market.
- 270. Not content merely to permit access to opioids, Express Scripts colluded with opioid manufacturers affirmatively to increase opioid prescribing. Since the release of OxyContin, Express Scripts conspired with Purdue in several crucial ways to expand opioid market and increase the sales and prescribing of OxyContin.
- 271. Medco partnered with Purdue on therapeutic exchange programs to increase OxyContin utilization during the years immediately following the drug's release. For example, in 1997-1998, Medco worked with Purdue to develop a "switch program" where pharmacies would switch out a competing product for OxyContin at the pharmacy counter. Purdue executive Michael Friedman explained the value of this program: "Medco is a huge customer and the potential gain from this effort could dwarf that of many other opportunities."³⁸
- In addition, during key years in the growth of OxyContin utilization, Medco also 272. worked with Purdue "behind the scenes" to get large health plans to lift restrictions—such as prior authorizations and quantity limits—on OxyContin utilization. For example, a 2002 email reveals

³⁸ E513 00022558.

Medco and Purdue working together to prevent the implementation of a prior authorization (PA) that would have reduced the supply of prescription opioids:³⁹

To: Radlund, Julia[/O=PURDUE/OU=PURDUE US/CN=Sales and Marketing -

Field/cn=DCB07D6C]

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Cc: Nagorski, Lynn[/O=PURDUE/OU=PURDUE US/CN=Sales and Marketing -

Field/cn=9F4581F2]; Richards, Tim[/O=PURDUE/OU=PURDUE US/CN=RECIPIENTS/CN=CBCEAB1F]

From: Grayson, Mel

Sent: Wed 3/13/2002 9:31:10 PM

Subject: Concerns at MMMC

To All:

I met today with Ed Adamcik of MMMC. His major concern is to negotiate a new rebate contract. Ed says that the reason they have been able to keep various clients from placing a PA on Oxy has been the value of the rebates to them. If this is suddenly reduced, there may be more clients who might want to place a PA, or some other type of restriction on OxyContin.

- 273. To that end, in a telling exchange in 2002, when Highmark Blue Cross Blue Shield decided it would put a 300mg daily limit on OxyContin, Medco pushed back because this meant that Medco would lose rebates from Purdue. At the time, Purdue warned Medco that "[o]ur platform for rebates is to permit the patient to reach 320 mg/day of OxyContin," so if Highmark adopted a 300mg a day limit, Medco "will be loosing [sic] rebates for a mere 20mg/day differential." In order to rectify the situation, Ed Adamcik, Medco's Vice President of Contracting, then intervened and convinced Highmark to drop its daily dosage limit.
- 274. During this same time period, internal Purdue emails show how the data that Purdue received from Medco helped eliminate potential UM restrictions and further strengthen the partnership between these two companies. In 2003, Purdue's Medco Account Representative Bernadette Katsur stated:

"I do see tremendous value in the data that [Medco] is willing to provide. As he explained to me the large MCO's could be identified by number, and then he would be willing to discuss opportunities or concerns on a plan sponsor by plan sponsor basis. He would then be willing to work with me to develop individualized strategy for that

³⁹ PPLPC029000064034 (3/13/02).

account. That would mean pulling in Medco Client Manager as well as the local account executive. This type of working relationship has proven to be extremely successful with AdvancePCS. We have eliminated many attempts to [prior authorization] and place [quantity limits] on product through this type of process. We have not had that degree of intimacy with Medco, and I think that Ed [Adamcik] would be willing to take that leap with the understanding that the extra percentage is being paid for that purpose."⁴⁰

- 275. An exchange between Medco, UHC (Medco's largest client), and Purdue that same year, 2003, exemplified the ideas in Ms. Katsur's email above. In early 2003, Medco worked again behind the scenes with Purdue to convince UHC to double a contemplated quantity limit from 60 tablets per prescription to 124 tablets per prescription. Given the amount of OxyContin that was sold through UHC plans in 2003 and the years thereafter—nationally, in this District, and in Plaintiffs' Communities—convincing UHC to double its quantity limit to 124 tablets likely resulted in a substantial increase in OxyContin sales during crucial years when the opioid epidemic was taking hold.
- 276. Rather than implement standard protocols that it knew would limit OxyContin to narrow, appropriate usage, Express Scripts engaged in a pattern of deception (working in conjunction with the prescription opioid manufacturers and often using manufacturer-created data and information) in order to increase opioid utilization and their own profits.
 - Express Scripts Colluded with the Prescription Opioid Manufactures to 2. Expand the Prescription Opioid Market and Access to OxyContin Prescriptions In Plaintiffs' Communities By Thwarting the West Virginia Public Employees Insurance Agency From Requiring Prior Authorization for OxyContin At the Dawn of the Opioid Epidemic.
- West Virginia's Public Employees Insurance Agency ("PEIA") provides health 277. care coverage to state and local government employees and their families, with a total enrollment

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⁴⁰ PPLPC012000067648 (emphasis added).

of around 75,000 members, many of whom reside and receive prescriptions in Plaintiffs' Communities and this Judicial District.

- 278. In the early 2000s, concerned about the increasing numbers of addiction and deaths attributed to oxycodone in West Virginia, officials with the West Virginia PEIA raised concerns to Merck-Medco (now Express Scripts) about OxyContin's dangerous and addictive nature and attempted to limit its use by requiring that prior authorization be implemented for OxyContin prescribing.
- 279. Faced with this threat to the expanding OxyContin market and corresponding lost profits, Purdue made it a top priority to thwart all efforts to limit, restrict, or control OxyContin prescriptions in West Virginia by PEIA or others, and then secretly acted in West Virginia to achieve this objective.
- 280. In a memo listing the 2001 goals of Purdue's West Virginia sales team, the first listed item under Medicaid is "Stop any preauthorization efforts for OxyContin."
- 281. In a separate memo, Purdue officials reported meeting with a state official to "interrupt" any efforts to require prior authorization of OxyContin.
- 282. And, in a presentation prepared for a 2001 West Virginia district sales meeting, a Purdue official wrote in regard to the state employee insurance plan that the company was "working with Medco (PBM) to try to make parameters less stringent."
- 283. To undermine and undercut efforts to impose pre-authorization for OxyContin, Purdue offered Merck-Medco—who was PEIA's pharmacy benefit manager at the time—and other PBMs lucrative quid-pro quo "rebates" conditioned upon them making OxyContin available without prior authorization and with lowered co-payments.
 - 284. Merck-Medco willingly cooperated.

- 285. PEIA Pharmacy Director, Felice Joseph, testified that when state officials asked Merck to put in place a plan to limit OxyContin prescribing, "they were [basically] refused."
- 286. The medical director for PEIA, Dr. Sandra Joseph, told a similar story in her deposition. "They felt strongly, and they were very, very reluctant or resistant, for whatever reason," she said of Merck. "They did not want to put any limits or prior authorization criteria on that."
- 287. Merck downplayed concern about OxyContin abuse, Joseph testified, saying the company "referred to other areas where there were not that many prescriptions for OxyContin, it was not that much of a problem." Merck's position to the PEIA was directly in contradiction to its previous position and actions back as early as 1997 when it warned its prescribers about the potential dangers and abuse potential of OxyContin.
- 288. It has been reported that a Merck official calculated that the company would lose \$128,000 in rebate payments if OxyContin prescribing was limited in West Virginia.⁴¹
- 289. Merck's and Purdue's actions are particularly troubling because, in public at least, they were carefully assuring authorities that they were working with state authorities to curb abuse of OxyContin. But, behind the scenes, however, as one Purdue official openly acknowledged, Purdue was "working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent."⁴²

⁴¹ https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/.

⁴² American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, Psychology Today (Oct. 28, 2016), https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic.

- 290. The strategy to pay Merck-Medco by Purdue in West Virginia extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin.
- 291. Merk-Medco's and Purdue's financial quid-pro quo agreement and conspiracy to expand OxyContin prescribing in West Virgina and eliminate pre-authorization occurred at a critical time in the opioid epidemic as it was taking root in Plaintiffs' Communities. Had Merck-Medco and Purdue not successfully conspired to expand the OxyContin market and prescribing in West Virginia, OxyContin would never have become widely available, other branded opioids and generics never would have followed the OxyContin wave, and the epidemic likely never would have happened in Plaintiffs' Communities.
 - C. For At Least Two Decades after Express Scripts Knew the Opioid Epidemic Was Occurring in Plaintiffs' Communities, Express Scripts Continued to Conspire with the Prescription Opioid Manufacturers in the Deceptive Marketing of Opioids.
- 292. Beginning in the late 1990s, prescription opioid manufacturers—including, but not only Purdue—engaged in a multifaceted campaign to expand the opioid market by creating and disseminating misinformation about the safety and efficacy of prescription opioids used in chronic pain treatment and the risks of prescription opioid addiction.
- 293. Express Scripts knew that there has never been reliable evidence demonstrating prescription opioids were safe or effective at treating chronic pain long term. Express Scripts further knew that prescription opioids, particularly when used long term to treat chronic pain carry serious risks of addiction. And yet, starting shortly after the release of OxyContin and continuing for years after the opioid epidemic was spreading throughout the country, this District, and in Plaintiffs' Communities, Express Scripts worked with the prescription opioid manufacturers in numerous capacities in furtherance of these efforts. In particular: (1) Express Scripts disseminated

the opioid manufacturers' false messages about chronic pain and addiction to high prescribers and patients, and (2) Express Scripts provided research, data, and consulting services to the opioid manufacturers to assist in expanding the opioid market.

294. As one type of example, Express Scripts (along with its subsidiaries – e.g., Express Scripts Specialty Distribution Service; Express Scripts SDS; HealthBridge, United BioSource LLC; Curascript, Inc.) partnered and/or collaborated with opioid manufacturers (e.g., Purdue, Endo) on Patient Assistance Programs ("PAPs") which provide free or low-cost medications to eligible individuals based on factors such as low-income and/or lack of health insurance. PAPs are "a triple boon for manufacturers" as they "increase demand, allow companies to charge higher prices, and provide public-relations benefits."

295. For more than two decades, from the mid-1990s through 2017, Express Scripts and/or its subsidiaries partnered and/or collaborated with Purdue on its PAP—which is significant in multiple respects: a) as Purdue's partner mail order pharmacy, Express Scripts dispensed 100 million+ opioid pills specifically for Purdue's PAP and it repeatedly did so in violation of the Controlled Substances Act ("CSA") (as discussed in greater detail below); b) since 2002 Express Scripts also administered Purdue's PAP, further establishing its collaboration and critical role in this early, continuing, and very successful marketing effort to increase utilization, drive volume, and facilitate access relative to OxyContin and other Purdue opioid products; and c) as a result of Express Scripts' integral involvement with Purdue's PAP, it was well aware of the addiction, abuse and diversion issues surrounding OxyContin and other prescription opioids since the mid-1990s.

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⁴³ Howard, David H., *Drug Companies' Patient-Assistance Programs – Helping Patients or Profits?* New England J. Med, 97, 97-99 (2014), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMp1401658.

296. Express Scripts and/or its subsidiaries played multiple roles (e.g., partner mail order pharmacy, program administrator, etc.) in Purdue's and Endo's respective PAP marketing schemes. The importance of Express Scripts is evident from internal emails. For example, a 1996 email outlined how Purdue's "IPAP usage[sic] has sky rocketed since [Purdue] instituted the Express Script policy," noting that "utilization has nearly quadrupled[sic]." ⁴⁴ In a subsequent email in the chain, a Purdue employee stated that "Express Scripts has made it much easier to get the free product, thus, some may be using it that wouldn't be before. For example, I can remember several instances where we were having difficulty getting retailers to participate in the program before Express Scripts." Moreover, as a result of Express Scripts' collaboration and work, Purdue's and Endo's respective PAPs were highly successful in increasing utilization, driving volume, and facilitating access relative to Purdue's and Endo's opioids, especially OxyContin and Opana.

297. Express Scripts' participation in the increasing opioid utilization and the fraudulent marketing of opioids continued even after Purdue pleaded guilty to criminal misbranding of OxyContin in 2007, as described above. Thus, even after Purdue acknowledged the falsity of its claims, Express Scripts, in collaboration with opioid manufacturers including Purdue, continued to spread the same misrepresentations about the safety and efficacy of opioids.

298. Express Scripts' participation in the fraudulent marketing of opioids continued long after its own data informed it that the huge increases in opioid prescribing were creating a crisis of addiction, overdose, and death across the United States, this District, and in Plaintiffs' Communities.

⁴⁴ PPLPC008000000530.

⁴⁵ *Id*.

299. Regardless of what Express Scripts knew or did not know at the outset of their marketing activities, it continued to engage in fraudulent marketing of opioids long past the point where it had actual knowledge of the falsity of the representations they were disseminating.

1. Express Scripts Disseminated the Prescription Opioid Manufacturers' Deceptive Propaganda.

- 300. Starting in the late 1990s—after granting Purdue's opioids preferred, unrestricted formulary placement in their standard offerings—Express Scripts partnered with Purdue and other opioid manufacturers to spread false information about opioids in order to increase opioid sales and expand the market.
- 301. For example, in 1999, Medco arranged for its pharmacists to be trained by Purdue's speaker consultants regarding chronic pain management and the use of OxyContin.
- 302. In 2003, internal Purdue documents show "[o]pportunities have been presented by Medco to work more closely with targeted clients within the marketplace on a client-by-client basis." These "opportunities" included developing educational programs to "stave off any formulary restrictions," disseminating Purdue created "educational" materials—including "New Perspectives on the Pharmacology of Opioids and Their Use in Chronic Pain" and Drug Diversion and Abuse: The Facts, Legal and Ethical Issues Affecting Pain Management: Fact or Fiction." Purdue provided this information to Medco to "be used with employers and managed care plans on the appropriate utilization of [Purdue's] products."
- 303. During these same years, along with Medco, Express Scripts was also Purdue's largest customer. Notably, Medco and Express Scripts remained Purdue's largest customer for OxyContin for the years up to and following the 2012 merger of these companies.

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⁴⁶ PPLPC012000064369.

304. And in similar fashion to Medco, Express Scripts also worked directly with Purdue in the critical years of OxyContin growth to expand the pain treatment market through the dissemination of misinformation about the use of opioids to treat chronic non-cancer pain.

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305. For example, in 2000 and 2001, Express Scripts worked together on numerous programs to disseminate "educational" materials to tens of thousands of patients and high prescribers of OxyContin advocating for opioids in chronic pain treatment and downplaying the risks of addiction. These programs included Express Scripts engaged in mass mailings of Purdue created propaganda such as "Dispelling the Myths about Opioids," "The Impact of Chronic Pain: An Interdisciplinary Perspective CME booklet," "Overcoming Barriers to Effective Pain Management," and "Use of Opioids in Chronic Noncancer Pain CME booklet." "These documents contained false information downplaying the risk of addiction and promoting the use of opioids in long term chronic pain treatment.

306. In one particularly telling internal Purdue "call note," a Purdue executive discussed "developing a piece on Opioid guidelines, [New England Journal of Medicine (NEJM)] quotes, and addiction terms." Notably, the "NEJM quotes" likely refer to a one-paragraph letter that was published in the *New England Journal of Medicine* reporting an observed low rate of addiction in patients prescribed opioids for short periods in an in-patient hospital setting. (Purdue and other opioid manufacturers misrepresented this letter as a "study" and claimed that it demonstrated that the risk of addiction to opioids was low when the drugs were prescribed for long-term, outpatient use.) The Purdue executive continued: "[l]egal has stated that [Purdue] representatives cannot utilize this [NEJM] piece. My thoughts are that this piece may be sent out by Express Scripts.

PPLPC029000016774; PPLPC029000020703;

PPLPC009000021694;

PPLPC009000021695; PPLPC029000040033; PPLPC029000040028.

Express Scripts and Purdue could target [family practitioner physicians and internal medicine physicians] who are the high writers of [DEA Schedule II and III drugs]. The mailer was intended to educate the physician on the beneficial uses of OxyContin and the preferred formulary status."⁴⁸

307. A number of these joint programs between Express Scripts and Purdue were prompted by Express Scripts' desire to work with Purdue to address the negative attention that OxyContin was receiving related to abuse and diversion in the early 2000s. For example, a March 14, 2001 letter from Express Scripts to Purdue explained "[c]learly with the market turbulence surrounding OxyContin you and your organization have significant demands on your time . . . there are several strategic initiatives where Express Scripts can support Purdue Pharma in your efforts to educate the market on the prescribing, administration and consumption of OxyContin."⁴⁹

308. These "strategic initiatives" proposed by Express Scripts included sending 15,000 "targeted" mailings to physicians which included a letter written by Express Scripts' Medical director summarizing key principles of the Purdue front group, American Pain Society, and included the Purdue-created brochures "The Patient Bill of Rights for Pain Management" and "Dispelling the Myths about Opioids" which contained misinformation about OxyContin risks, such as "addiction risk also appears to be low when opioids are dosed properly for chronic noncancer pain." ⁵⁰

309. An April 2001 Purdue memo further described the reasons behind Express Scripts and Purdue's collaborations at that time: "[Express Scripts] has told us that this mailing is necessary so that [Express Scripts] may squelch the anti-OxyContin pushback from their clients

⁴⁸ PPLPC009000021694; PPLPC009000021695.

⁴⁹ PPLPC028000031679.

⁵⁰ PPLPC028000031679.

(Managed Care Organizations and Employer Groups) due in large part to the national media attention OxyContin is receiving."⁵¹

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- 310. Purdue's and Express Scripts' joint efforts to expand the opioid market continued in the summer of 2001, when they used an Express Scripts "proprietary database" to identify the top 1,900 physicians with high prescribing rates for Schedule 2 narcotics and then mailed these 1,900 physicians materials created by the front-group American Pain Society ("APS"). The mailed APS material promoted use of pain scales and the debunked, industry-advocated concept of pseudo-addiction.
- 311. Express Scripts and Purdue's collaboration continued through 2004, when Express Scripts and Purdue developed a series of pain management presentations for an Express Scripts' clients, to be conducted by Purdue's Medical Liaisons, who were doctors and medical professionals employed by Purdue to promote opioid therapy.
- 312. To assist in the marketing efforts of opioid manufacturers, Express Scripts has for years provided multiple opioid manufacturers with lists of all their plan clients as well as the names of physicians who were participating in the plan's provider networks. The manufacturers used this information to target the highest opioid prescribers with pull-through marketing.
- 313. For example, according to one 2011 email, Endo sales representatives were instructed to "[m]aximize pull-through with key managed care plans," "[d]rive brand awareness across top [Opana ER] prescribers," and promote favorable Opana ER formulary positioning.⁵² Sales representatives were also told to focus on providers "that have the most potential" and not

⁵¹ PPLPC029000040033; PPLPC029000040028.

⁵² ENDO OPIOID OHAG-00030138 (1/14/11).

"waste time" on other physicians.⁵³ Sales representatives also were dispatched to (and did) promote Opana ER formulary status to prescribers.

In addition, beginning in 2006, Express Scripts and Purdue entered into an ongoing 314. "Participating Manufacturer Agreement" under which, in return for "administrative fees," Express Scripts would

. Express Scripts would also conduct "physician education with respect to Formulary products." And, Express Scripts agreed it they would provide numerous deliverables to Purdue, including which enabled Purdue to more effectively pull through its drugs' formulary status to physicians. The "administrative fees" Express Scripts received were tied to the number of opioids it sold—i.e., the more opioids it sold, the more it made. This agreement was strictly confidential. Express Scripts and Purdue renewed this agreement on at least three occasions, and it was in place until at least the end of 2010.

- In 2011 and 2012, Express Scripts and Purdue collaborated on false and misleading guidelines for workers' compensation patients to promote "safe and effective chronic opioid therapy."54
- 316. In fact, as late as 2017, Express Scripts gave educational presentations on pain management that treated the risk of addiction to opioids as minimal. In a presentation regarding "The Management of Persistent Pain in Older Persons," Express Scripts Vice President Andrew Behm asserted that psychological dependence to narcotic analgesics was "rare" and that

⁵³ ENDO TXMDL 00448429 (10/4/09).

⁵⁴ See PPLPC012000368690 (3/8/12); PPLPC012000368687 (3/8/12).

"Addiction associated with the appropriate use of opioid analgesics is uncommon." 55 The presentation also described "physical dependence" as "common" and a "state of adaptation to chronic opioid therapy," and recommended fentanyl for chronic pain in older adults. ⁵⁶

- 2. Express Scripts' Affiliated Entities Provided Research, Data and Consulting to Prescription Opioid Manufacturers to Expand the Prescription Opioid Market.
- In addition to assisting the prescription opioid manufacturers in spreading false 317. information about prescription opioids, for years Express Scripts and its affiliated companies provided the prescription opioid manufacturers with data, research, and consulting services needed to expand the prescription opioid market.
- 318. For example, in the late 1990s and early 2000s, Express Scripts' affiliate research entity, Practice Patterns Sciences, Inc. ("PPS"), and Medco's Institute for Effectiveness Research provided research and studies for Purdue in to aid its efforts to expand the opioid market. One example occurred in 2001, when Express Scripts/PPS developed a study for Purdue on "The Value of OxyContin Therapy in Patients with Moderate to Severe Pain due to Osteoarthritis."57
- In sum, the opioid manufacturers' efforts to disseminate misinformation about 319. opioid addiction, opioid use for chronic pain, and opioids as a first-line therapy inappropriately expanded the opioid market. And since the 1990s, Express Scripts collaborated with Purdue to spread this misinformation in an effort to increase opioid utilization and sales. The result of these joint efforts (in Express Scripts own words) was the "opiate explosion: vast increase in prescribing [and] more potent formulations [of opioids]."58

⁵⁵ ESI JEFFCOMO 000012632, at slide 56 (4/24/17).

⁵⁶ *Id*.

⁵⁷ PDD8801105525.

⁵⁸ ESI JEFFCOMO 000032900.

D. Express Scripts Had Access to Real-Time Data Regarding Drug Utilization Which Gave It a Unique Vantage Point into the Opioid Epidemic.

- 320. Express Scripts has had a front row seat to the spread of the opioid epidemic. It was the number of opioids prescribed and dispensed has exploded. It was made aware of the opioid epidemic through the vast amount of data it possessed; the knowledge gained through its clients, manufacturers, and other entities in the health care arena; and through clinical evaluations for things such as formulary placement.
 - 1. Express Scripts tracks every prescription claim it processes across all the health plans it services which provided it with uniquely granular and comprehensive data.
- 321. Because of its business model, Express Scripts has access to an extraordinary amount of data. Express Scripts can not only see detailed information on individual prescribers and pharmacies, but can also aggregate that data across manufacturers, patients, pharmacies, and payors. Its visibility into this data is thus both uniquely granular and comprehensive.
- 322. This data includes information such as the volume, nature, dosage, and conditions for which health care providers are prescribing opioids to individual patients and on an aggregate basis; the volume of prescription opioids obtained by individual patients and by geography; the pharmacies at which prescription opioids were dispensed and the volume of opioids dispensed by geographic area, among other data. Express Scripts also had data from its own mail order pharmacies.
- 323. For the past two decades, Express Scripts has processed approximately 8 to 10 million prescription claims per day—1.4 billion claims per year—for its members with hundreds of data points for each transaction. At all times since the 1990s, Express Scripts has had as much—if not more—detailed claims data on opioid utilization and prescribing than any other entity in the pharmaceutical industry.

- 324. Express Scripts not only collected prescription data, but also analyzed it to track utilization patterns. Since 1997 Express Scripts has compiled in-depth drug utilization analyses of its own claims data from millions of Express Scripts' members across the country in its Drug Trend Reports. Starting in at least 1999, Express Scripts Drug Trend reports reflected both Express Scripts' knowledge of increasing OxyContin and opioid utilization, as well as its understanding of the dangers of these drugs.
- 325. Express Scripts' ability to monitor and analyze opioid prescription data is exemplified by its 2014 "A Nation in Pain" report focusing on the opioid epidemic. The report reviewed 36 million pharmacy claims from 2009 to 2013, which illustrated the widespread opioid epidemic. In the report, ESI demonstrated its ability to identify opioid use trends by geography, age, and gender, as well as by the prevalence of doctor and pharmacy shopping and drug cocktail use.
- 326. Because of all of the data it possessed, Express Scripts was aware that the volume of opioids being prescribed in the United States, and in Plaintiffs' Communities, far exceeded an amount that could possibly be justified as medically necessary or appropriate. It knew that opioids were being overprescribed and used inappropriately, and that Plaintiffs' Communities were being flooded with an oversupply of these dangerous drugs.
- 327. To make matters worse, rather than use its data to stop the public health crisis that it was watching unfold, since at least 1997, Express Scripts sold its detailed claims data, as well as its clients' formulary and health plan information, to Purdue and other opioid manufacturers. The opioid manufacturers then used this data to gain insight into the pharmacies and health care providers who were dispensing and prescribing their opioids (as well as their competitor's products) and more importantly those pharmacies and prescribers who were not prescribing and

dispensing their products. This allowed sales representatives of Purdue and the other opioid manufacturers to have laser precision targeting high prescribers and pharmacies in order to aggressively push opioids onto the market.

328. For as long as it has been a PBM, Express Scripts received, compiled, and analyzed massive amounts of prescription claims data demonstrating that opioids were being over-utilized, abused, and diverted. Indeed, Express Scripts had more data on and awareness of the opioid epidemic unfolding than any other entity in the pharmaceutical industry. It knew or certainly should have known for decades that opioids were causing a public health crisis.

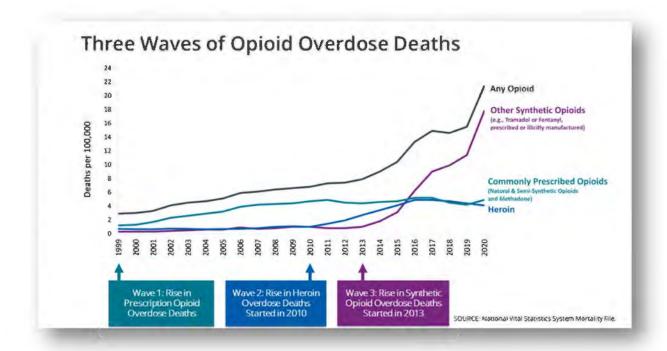
2. Express Scripts had knowledge about the opioid epidemic and about abuse and diversion.

- 329. According to the CDC, the rise in opioid overdose deaths can be outlined in three distinct waves. As the CDC explains: "The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since at least 1993. The second wave began in 2010, with rapid increases in overdose deaths involving heroin. The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl."⁵⁹
- 330. Very recently, as of September 2023, the United States has entered the Fourth Wave of the Opioid Epidemic. A study⁶⁰ released by the Center for Social Medicine and Humanities, University of California, Los Angeles, California, USA, found that "recently, scholars have argued that the 'fourth wave' of the US overdose crisis has begun, in recognition of rapidly rising

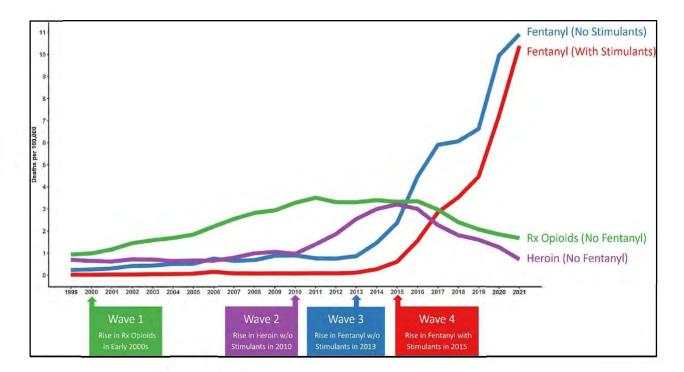
⁵⁹ OPTUMRX JEFFCO 0000360074.

⁶⁰ Friedman, J, Shover, CL, Charting the fourth wave: Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010–2021, 118 ADDICTION 12 (Dec. 2023), https://doi.org/10.1111/add.16318.

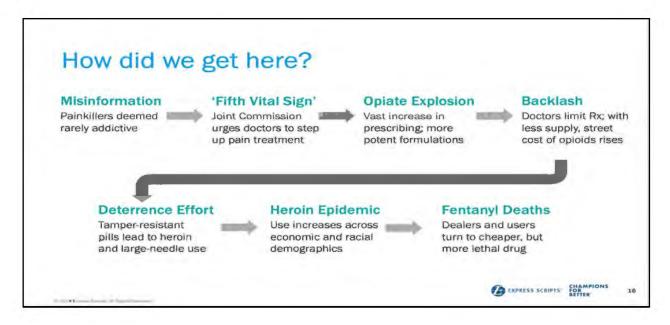
polysubstance overdose deaths involving illicitly manufactured fentanyl, with stimulants playing a key role. By 2021, methamphetamine and cocaine were the only leading co-involved substances as depicted below. This represents current 2021 trends, a culmination of a long road of crisis level addiction beginning with *prescription opioid abuse*.



331. The following chart, depicting "Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010–2021" shows the four waves of the epidemic:



332. Express Scripts own marketing material explicitly recognized this evolution in the national opioid crisis:⁶¹



333. Long before the second wave of the crisis started in 2010, Express Scripts knew that opioid abuse and misuse posed serious problems.

⁶¹ ESI_JEFFCOMO_000032900.

- 334. Express Scripts knew that opioids were addictive and carried a significant risk of serious injury or death, and they have known this for at least the past 20 years.
- 335. For example, Medco informed Purdue that they had concerns about the potential for abuse in OxyContin right out of the gate in 1997.
- 336. Similarly, starting in at least the early 2000s, certain Express Scripts and Medco clients also began to express concern to them about abuse and diversion issues related to OxyContin. Upon hearing from their clients, Express Scripts and Medco would often reach out to Purdue directly seeking help to quash these concerns. Purdue often worked with Express Scripts by providing research and "educational" materials downplaying the risks associated with prescription opioid use.
- 337. For example, in 2002, internal Purdue emails describe a call with Medco regarding clients who "had concerns about tablet restrictions and proper utilization of OxyContin." Medco informed Purdue that "an overview of the abuse and diversion issue surrounding OxyContin would be helpful for [Medco] to respond to their customers questions/concerns."
- 338. In 2003, Medco's largest client, UHC, expressed concerns that "there were patients taking 960-1000 tabs of OxyContin per month" and stated that it wanted to act "to reduce the abuse and diversion issues." Following this, Medco and Purdue worked together to compile research and data to provide to this client to alleviate these concerns.
- 339. Also in 2003, an Express Scripts employee gave a presentation at a 2003 conference in which that employee, while discussing OxyContin, stated, "This is a narcotic. All narcotics are addictive. In addition, this is a controlled release narcotic, so when someone would crush it up and

⁶² PPLPC029000063491.

⁶³ E01 00004716.

either ingest it or inject it there was a potential for serious injury or even death."⁶⁴ This same Express Scripts employee also indicated that because patients were becoming tolerant, chronic use of opioids was occurring and patients were taking increasingly higher doses over time (sometimes referred to as "dose-creep" or "dose-creeping"). ⁶⁵ Following a study of opioid use in a private plan that revealed this pattern, Express Scripts conducted an internal study and "found that similar patterns were occurring . . . across ESI's book of business."⁶⁶

340. Express Scripts also knew or had reason to know that opioids were being improperly marketed. They were aware, for example, that the price of at least some opioids (including OxyContin) increased as dosage increased. And when describing this dose-creeping phenomenon during the 2003 conference, an Express Scripts employee suggested that this phenomenon is not merely attributable to tolerance from chronic use—he said dose-creeping "may be reflective of detailing for this drug." Indeed, a Purdue employee who attended this conference said in an email to other Purdue personnel that "[Express Scripts] is looking at the detailing of the drug. [Express Scripts] implied that there may be improper detailing by the manufacturer."

341. Express Scripts also knew that prescription opioids were being improperly marketed because, in 2007, Purdue pleaded guilty to criminal misbranding of OxyContin. The plea agreement identified specific representations that Purdue acknowledged were false. Express Scripts knew that these same misrepresentations were still being used by Purdue and others in the

 $^{^{64}}$ See PPLPC012000061345, 13486 (6/5/03) (family).

⁶⁵ *Id*.

 $^{^{66}}$ *Id*.

⁶⁷ *Id*.

 $^{^{68}}$ *Id*.

marketing of prescription opioids. Yet it failed to use their standard formulary and UM offering to counteract the effects of this fraudulent marketing.

342. In 2006, Express Scripts executives again recognized the risk of abuse opiates posed. But Express Scripts was reluctant to implement more robust monitoring for fear of customer blowback and loss of prescription volume:⁶⁹

From: Behm, Andrew (BLM)

Sent: Monda To: Gross,

Subject:

Monday, August 14, 2006 2:08 PM Gross, Amy (BLM); Colby, Andrew J. (STL) RE: Retro DUR Addictive Substances question

No Stadol. We previously targeted all controlled substances plus Tramadol, Soma, and combos of those products.

When we enhanced the targeting, CPMs were only really interested in the oplates from an abuse perspective. I suppose we could revisit the targeting — especially if you're aware of any new feedback — but that will definitely impact the number of letters and volume.

343. As early as 2008, Express Scripts acknowledged the acute diversion risk with opioids. For example, Express Scripts employee Adam Kautzner (now its President) noted the "improved street value" of brand name narcotics:⁷⁰

From: Kautzner, Adam W. (EHQ)

Sent: Tuesday, November 04, 2008 11:32 AM To: Gross, Amy (BLM); Martin, Jason (STL)

Cc: Boike, Jackie L. (BLM)

Subject: RE: file on temp transfer drive

I was afraid this was going to be your response!

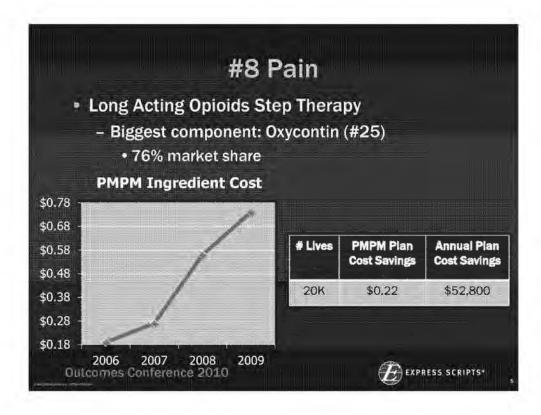
Brand name narcotics may especially be interesting with their improved street value.

I will dig in my email archives for requests but haven't had many lately. Especially for QLLs.

⁶⁹ ESI JEFFCOMO 000260226 (8/14/06).

⁷⁰ ESI_JEFFCOMO_000273681 (11/4/08).

344. The following slide was included in a client-facing presentation discussing the 2008 Express Scripts Drug Trend Report. The slide included speaker notes acknowledging Express Scripts' own awareness that in 2008 it needed to do something about OxyContin abuse: "We all know the abuse potential for [Oxycontin] and we knew that a solution needed to be offered to all of you here if you wanted to address it:"⁷¹



345. In 2009, Express Scripts received an email from a client stating, "Houston, we have a problem, and its name is Oxycontin." That same year another large client reached out to Express

⁷¹ ESI JEFFCOMO 000278190; ESI JEFFCOMO 000278192.

⁷² Gross Dep. 55-56, Ex. 4; *see also* Gross Dep. 74 (discussing exhibit in same time period where ESI clinical personnel observed that "there has been quite a bit of client buzz around increasing Oxycontin use")).

Scripts regarding its desire to put into place an "aggressive PA policy" on prescription opioids to combat "rampant abuse and inappropriate" opioid use.⁷³

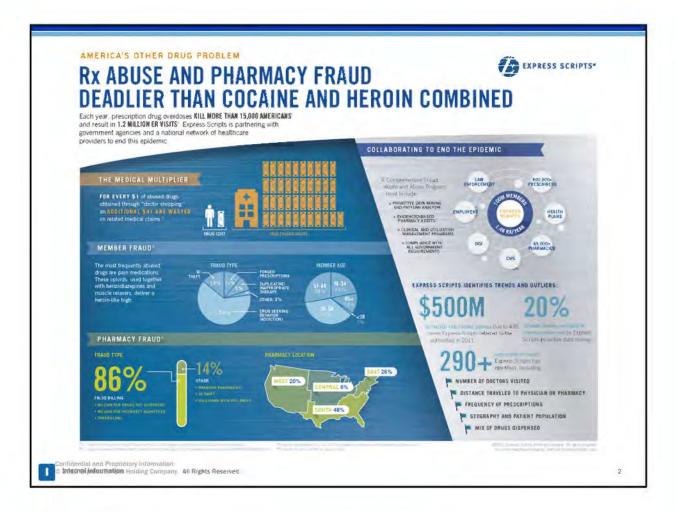
346. Another example occurred in 2011, when Express Scripts Vice President of Clinical Evaluation & Policy wrote to the chair of one of Express Scripts formulary committees, stating:

I think the overutilization of opiates continue to be a significant problem. From what I've heard, there are thoughts out there that the opiates are being greatly over-utilized by patients with chronic non-cancer pain . . . MDs should be pushing for more non-opiate pharmacotherapies and non-pharmacologic options.⁷⁴

347. In 2013, Express Scripts put together the following client-facing marketing poster utilizing its own data, as well as outside sources, that not only recognized that opioid abuse was "deadlier than cocaine and heroin combined" but also recognized the pivotal role that Express Scripts plays in "collaborating to end the epidemic":

⁷³ ESI JEFFCOMO 000259907.

⁷⁴ ESI_JEFFCOMO_000299137.



- 348. Express Scripts' 2014 report, "A Nation in Pain," concluded, among other things, that "[p]rescription rates for opioids increased dramatically in the past two decades . . ." and that "[o]pioid abuse is an epidemic in the U.S." "A Nation in Pain" also referenced a separate ESI study that found that 40% of opioid prescriptions filled by members with employer-sponsored drug coverage between 2011 and 2012 were written by only 5% of prescribers. ⁷⁶
- 349. Express Scripts knew about the epidemic not only from its own data, but from other sources as well. One of these sources was almost surely their own P&T committees. These

⁷⁵ "A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain, An Express Scripts Report," (Dec. 2014), https://d11tr245s7jfj6.cloudfront.net/2019-08/Opioid%20Report_0.pdf.

⁷⁶ ESI_JEFFCOMO_000003092 (12/9/14).

committees have historically been concerned with "the documented safety and efficacy of new drug formulations." P&T committees are typically "comprised of physicians, pharmacists, and other clinicians" that meet regularly to keep up with the fast pace of pharmaceutical innovation. Express Scripts, for example, describes its P&T Committee as "a panel of independent physicians and pharmacists in active clinical practice, representing a variety of specialties and practice settings and typically with major academic affiliations."

350. The University of Wisconsin-Madison Division of Pharmacy Professional Development lists, among its "5 Best Practices for P&T Committee Members," the need for committee members to "be informed," "be objective," and "emphasize patient-focused outcomes." In particular, to stay informed, "[t]hey should regularly seek out information from reputable sources, including peer-reviewed journals, industry thought-leaders and the FDA." With respect to being objective, the Division notes that "[f]ormulary decisions are objective and evidence-based." When discussing the focus on patient outcomes, P&T committee members "should be focused on the quality, efficacy, and safety of the treatment patients receive."

⁷⁷ Zhixiao Wang et al., "Cost-Effectiveness Analysis and the Formulary Decision-Making Process," *Journal of Managed Care Pharmacy*, Vol. 10, no. 1, pp 48–59 at p. 48 (Jan./Feb. 2004).

⁷⁸ Peri Iz, "Study of Pharmaceutical Benefit Management," PricewaterhouseCoopers HCFA Contract No. 500-97-0399/0097, p. 79 (June 2001).

⁷⁹ Express Scripts Holding Company, 2017 SEC Form 10-K, at p. 5 (Dec. 31, 2017) https://www.sec.gov/Archives/edgar/data/1532063/000153206318000004/esrx-12312017x10k.htm.

⁸⁰ UW-Madison School of Pharmacy, Division of Pharmacy Professional Development, 5 Best Practices for P&T Committee Members, (Sep. 25, 2023), https://ce.pharmacy.wisc.edu/blog/5-best-practices-for-pt-committee-members/.

⁸¹ *Id*.

 $^{^{82}}$ *Id*.

 $^{^{83}}$ *Id*.

- 351. Given this responsibility to stay informed, P&T committee members knew or should have known of the nationally available information regarding the risks of opioids. And through these P&T committees, Express Scripts knew or should have known that information throughout the relevant time period.
 - 3. Express Scripts Failed to Timely Undertake Actions to Address the Opioid Epidemic It Helped Create in Plaintiffs' Communities.
- 352. Express Scripts not only had knowledge of the dangers of prescription opioids, it had the ability and the opportunity to rein in prescription opioid access, but chose not to.
 - a. Express Scripts chose not to use its claims data and formulary, and/or UM offerings to address overprescribing, abuse and diversion.
- 353. Claims data available to Express Scripts gave it the ability to identify prescription opioid abuse and fraud. Having individually identifiable information for patients, physicians, and retail pharmacies allowed Express Scripts to analyze opioid utilization, patterns, and abuse. Yet despite having an array of available, commonly used tools to detect physician overprescribing and manage patient drug utilization, Express Scripts failed to timely implement opioid limits that would have drastically reduced the inappropriate prescribing and dispensing of opioids, and failed to reveal what they knew from the data they collected and analyzed so informed decisions could be made about ongoing dispensing practices and system-wide abuses. Moreover, Express Scripts was at the same time contracting with opioid manufacturers for payments of rebates and fees based on utilization, without restriction, of opioids.
- 354. Express Scripts has been on notice for decades that they needed to and had the ability to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis.

- 355. For instance, Express Scripts' own studies dating back to at least 2002 demonstrated the effectiveness that UM tools such as prior authorizations had at decreasing inappropriate opioid overutilization.
- 356. In 2002, Express Scripts researchers conducted a study to "examine the clinical and economic outcomes associated with a prior authorization (PA) requirement for OxyContin." The results of the study were: "post (PA) implementation PMPM claims and expenditures for OxyContin decreased significantly without an increase in PMPM trend. The PMPM trend in claims for other C-2 narcotics slowed. Results indicated that those who obtained PA approval were more likely to have had a pain-related diagnosis than those who did not attempt PA approval but there was no difference in pain-related health services use between the groups after PA implementation." In other words, Express Scripts' own research conducted in 2002 demonstrated that prior authorization significantly decreased inappropriate OxyContin utilization.
- 357. In response to this study, Purdue executives expressed concern that the study may decrease OxyContin utilization: "The emphasis [that the study] placed on statements about areas of tolerance, safety, abuse and detailing of the product may have left the impression that other ESI Medicaid and commercial clients should consider implementation of a similar restriction on OxyContin."
- 358. That same year, in 2003, describing how opioids were dispensed to Medicaid patients in the State of Georgia, one ESI employee noted how the deployment of a prior authorization process significantly curtailed OxyContin use in that state:

Now for this particular program there was a special kind of PA [prior authorization] [for opioids] and it included quantity level limits. So what was happening in this PA was that a patient would call-in for the approval and at that time depending on their indication for short-

⁸⁴ Henderson Dep. Ex. 18; Henderson Dep. Ex. 19.

term pain such as a fracture or long-term pain such as cancer, they would get the length of the amount of refills they get. So for the short-term they would be allotted two one-month refills for the drug. For the long-term pain they would get up to six one-month refills for the drug. So . . . we looked at the outcomes and in this case we examined pain related emergency room visits. Now understandably this is not the best way to assess a pain outcome, but we had limited data, we had to do a retrospective analysis. If we had been able to do it prospectively we would have looked at things such as quality of life and activities of daily living. 85

359. The result of this PA program was that, "For this client, this plan, Oxycontin went from ranked number seven to number 14 in drugs spent after the PA implementation." Importantly, Express Scripts "found that [these] patients who did not receive the Oxycontin did not have a greater use of medical services[,] so there was not an unintended medical consequence from this program." And not only did Express Scripts "think this [Georgia] program worked," but it also declared that "this isn't just exclusive to [Express Scripts], but any PBM should be doing these things." Unfortunately, it was not until fourteen years later that Express Scripts started to push clients to implement systemic opioid management tools.

360. In 2006, Express Scripts again conducted a study on its Medicaid population that showed the effectiveness of PA's on reducing Oxycontin utilization. Specifically, a state-run Medicaid program had been concerned about the chronic use and potential abuse of OxyContinTM, a Class 2 narcotic. Express Scripts also noted that "media and legislators had raised questions regarding potential abuse of OxyContin. Express Scripts implemented a prior authorization to "limit the medication to only those patients with a demonstrated medical need" and incorporated

⁸⁵ PPLPC012000061348 (6/4/03).

⁸⁶ *Id*.

⁸⁷ *Id*.

⁸⁸ *Id*.

a quantity limit. At the end of a year of this program, Express Scripts found that "patients who requested a prior authorization were more likely to have a pain-related diagnosis than those members who did not request a prior authorization after being denied at the pharmacy." Express Scripts also concluded that the "prior authorization program addressed this Medicaid program's goal of fostering appropriate pain management while not increasing the use of emergency services for pain."

- 361. Despite knowing for decades that prior authorizations were a best practice for preventing opioid overutilization and abuse, Express Scripts failed to create or offer a standard prior authorization protocol on opioids to its clients until 2017—after the Senate had contacted Express Scripts (twice) regarding its role in the opioid epidemic.
- 362. To make matters worse, Express Scripts had considered implementing a prior authorization on opioids as early as 2007. Internal Express Scripts documents reveal that Express Scripts had received "requests in 2007 for [point of sale] programs for inappropriate narcotic utilization . . . [because] a more robust standard program covering all narcotics was desired." Express Scripts elected not to pursue this program.
- 363. Indeed, when the FDA in 2013 removed the indication for use of long-acting narcotics to treat moderate pain, Express Scripts admitted, "we don't really have a standard OxyContin PA program. Our current UM strategies are more focused on driving preferred products and managing quantities."

⁸⁹ ESI_JEFFCOMO_000306081.

⁹⁰ ESI JEFFCOMO 000273099; ESI JEFFCOMO 000273100.

⁹¹ ESI_JEFFCOMO_000169781 (9/11/13).

364. Prior to 2017, whenever Express Scripts was questioned by federal or state governments or its own clients on what it was doing to combat opioid abuse, they pointed to its step therapy policy on long-acting opioids ("LAO"). This policy required a patient to try a generic opioid before the patient could be dispensed a brand opioid.

365. However, Express Scripts knew its LAO step policy was not created to address opioid overutilization or abuse. Rather, it was merely a cost containment and stockpiling/waste measure. In fact, in 2011, Express Scripts Vice President of Clinical Evaluation & Policy, Andrew Behm, wrote to Express Scripts Clinical Director Amy Gross asking whether the following statement in the draft Drug Trend Report was true: "Possible abuse continues to concern plan sponsors. In 2010, Express Scripts initiated a long-acting opioid strategy designed to ensure that published pain-treatment guidelines are followed." Amy Gross responded:

What??? The [long acting opioid step therapy policy] has nothing to do with pain treatment guidelines. It is just generic before brand. Then we updated the OxyContin [Drug Quantity Management] to include the other long-acting meds. But again not to ensure published treatment guidelines were follow. I HATE this sentence. . .The [Step Therapy] and [Drug Quantity Management] are in place for cost-containment (generic before brand) and stockpiling/waste. 92

366. On its face, it is clear Express Scripts' long-acting step therapy policy was never intended to limit opioid overutilization or abuse. Generic versions of the long-acting opioids are just as addictive as the brand versions. Stepping from a generic version to a brand did not promote effective use of opioids; rather it opened the gates to the use of generic long-acting opioid given that for the most part generic versions of these drugs were unrestricted, Tier 1 status on Express Scripts' standard formularies.

⁹² Gross Dep. Ex. 4.

- 367. Express Scripts could have created a policy where the Step 1 drug for certain patients was a non-opiate product. Indeed, the same year that Express Scripts implemented its LAO step policy, Express Scripts Vice President of Clinical Evaluation & Policy, Andrew Behm acknowledged that "overutilization of opiates continue to be significant problem" and recognized that "non-opiate pharmacotherapies" should be promoted. 93 Yet, Express Scripts failed to offer a non-opiate step and opted instead to create a policy that substituted an opioid for another opioid.
- 368. Express Scripts also failed to implement this policy during crucial years when the opioid epidemic was taking root as brand opioids (such as when OxyContin which was released in 1996) were expanding the pain treatment market and were being heavily abused and diverted. Had Express Scripts implemented a step therapy policy in the early 2000s that shifted utilization from brand opioids to non-opioid pain treatments it could have had a significant impact on the opioid epidemic in Plaintiffs' Communities. But Express Scripts failed to do so.
- 369. By the time that Express Scripts enacted its long-acting opioid step policy, its financial incentives with respect to opioids had shifted and Express Scripts was making more money on generic opioids.
- 370. Therefore, while Express Scripts long-acting opioid policy did nothing to address the opioid epidemic, it did shift utilization from addictive brand opioids to equally addictive generic opioids that were more profitable for Express Scripts.
- 371. To make matters worse, prior to 2017, Express Scripts knew that the programs it ostensibly had in place to address opioid overutilization were failing. For example, a 2015 email from the head of Express Scripts' eFWA program to Express Scripts Vice President of Clinical Evaluation & Policy stated:

⁹³ ESI_JEFFCOMO_000299137.

[Express Scripts Fraud, Waste, and Abuse Department] have been seeing way to many egregious drug seeking activity over the years. So much so that it is hard to defend how our systems would allow 68 control scripts by 47 physicians, and 28 pharmacies in a year for one patient. *This is one of many that we use as examples*. My thought is to try to fix this issue as well as the patient safety concern on the front end. Who could I work with around the control substance logic at POS edit? There has to be something to stop this proactively. ⁹⁴ (Emphasis added).

- its data mining and analytics tools for its client benefit plan found that one plan member filled 49 opioid prescriptions from 14 prescribers at 6 pharmacy locations in 14 months' time.

 Another member had filled 36 opioid prescriptions in just one year's time, including some 1,898 dosage units (749 days' worth) in just one year. Yet another member filled 29 opioid prescriptions in just 5 months' time. Despite these clear examples of gross over-dispensing, Express Scripts refused to change course and implement programs that it knew would have reduced inappropriate opioid utilization such as prior authorizations.
- 373. Had Express Scripts created and offered a robust prior authorization program on opioids in 2007 it likely would have resulted in tens (if not hundreds) of millions of fewer opioids being dispensed throughout the country, including in Plaintiffs' Communities.
- 374. Beyond prior authorizations, by no later than 2011, Express Scripts had been put on notice by the Centers for Medicare and Medicaid Services ("CMS") that all actors involved in delivery of healthcare in the United States needed to take steps to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis.
- 375. In September 2011, CMS sent a memorandum to "All Part D Sponsors" (which included Express Scripts and/or its predecessors-in-interest) describing the agency's desire to work

⁹⁴ Nader Dep. Ex. 10.

with them to develop policies and procedures to significantly reduce opioid abuse. This notice advised all recipients that Medicare data show overutilization of prescription opioids that is "highly indicative of drug seeking behavior due to drug abuse or diversion." Express Scripts received the notice and was aware of the need to take action to address the opioid crisis through the use of utilization management tools. While CMS acknowledged that some Part D sponsors were employing "claim-level" controls to try to prevent opioid misuse, CMS advised that these measures do not adequately address the opioid overutilization that concerned CMS and suggested that "beneficiary-level controls" are needed, including clinical upper thresholds for appropriate dosing, beneficiary-level utilization reports that identify unusual patterns of opioid use, and denial of payment for any claims that reflect amounts in excess of appropriate clinical thresholds that cannot be justified after review. 97

another notice in December 2011. 98 CMS assured sponsors in this notice that prompt pay regulations are not an impediment to their efforts to reduce overutilization and diversion of opioids because those regulations only apply to "clean claims" while prescriptions that raise concerns—for example, because they would exceed appropriate clinical thresholds—are not "clean." This notice also encouraged sponsors, including Express Scripts, to self-report instances of potential fraud or abuse (*e.g.*, drug-seeking behavior) and noted that mandatory reporting may be the subject

⁹⁵ See ESI_JEFFCOMO_000262220 (1/25/12).

⁹⁶ *Id*. at 1.

⁹⁷ *Id.* at 1-2.

⁹⁸ See ESI JEFFCOMO 000262863 (1/16/12).

⁹⁹ *Id.* at 1-2.

of future rule-making.¹⁰⁰ And CMS also advised sponsors that, while wholesale prior authorization requirements may not be implemented for "protected class drugs," sponsors can "conduct retrospective reviews on . . . protected class drugs," and where such a review reveals that opioids are being diverted or misused, the sponsor "can require documentation to determine medical necessity and may deny payment for subsequent claims if insufficient evidence is obtained to substantiate" the legitimacy of the prior opioid prescriptions.¹⁰¹ This notice further reminded sponsors, including Express Scripts, that it "may conduct appropriate consultations with physicians regarding treatment options and outcomes."¹⁰² Finally, the December 2011 CMS notice suggested that sponsors should "encourage prescribers to prescribe in less than 30 days supplies" and "promote less than 30 day prescribing of drugs that are more susceptible to abuse or diversion, especially opioids."¹⁰³

377. Likewise, in June 2012, CMS issued a draft guidance on improving drug utilization review controls. ¹⁰⁴ In this guidance, CMS explained that, because of sponsor comments seeking clarification of what is expected, CMS was providing a "sample program" and "additional detail" on "how such a program could be implemented." ¹⁰⁵ This sample program called for, among other things:

(a) Written policies and procedures that are updated and reviewed by plan's P&T Committee;

 $^{^{100}}$ *Id.* at 2.

 $^{^{101}}$ *Id*.

¹⁰² *Id*. at 2.

 $^{^{103}}$ *Id*.at 3.

¹⁰⁴ See ESI JEFFCOMO 000022947 (7/5/12).

 $^{^{105}}$ *Id.* at 1.

- (b) Establishment of "methodology to identify potential opioid overutilizers based on drug claims data through clinical thresholds and prescription patterns set by the P&T committee that would trigger case management;"
- (c) A protocol to exclude from retrospective review persons who truly need significant amounts of opioids (cancer patients, palliative care);
- (d) Regular communication with prescribers and beneficiaries about case management actions;
- (e) A process for data sharing among sponsors when beneficiary/patient disenrolls voluntarily from a plan; and
- (f) Policies and procedures for reporting to appropriate agencies when overutilization occurs. 106
- 378. The CMS guidance also included sample form communications that sponsors can use in implementing programs to prevent overutilization and diversion of opioids. ¹⁰⁷
- 379. However, even with CMS calling attention to Express Scripts' role and responsibility to prevent opioid misuse, Express Scripts' internal resistance to implementing policies and procedures to significantly reduce opioid abuse continued for years.
- 380. Express Scripts resisted limits that threatened rebates and other fees. For example, in a 2017 email chain, several Express Scripts employees derided the fact that the effort to put a prior authorization limit on OxyContin had been overruled by the ESI Value Assessment Committee. Janelle Kuntz, the Express Scripts Clinical Director for the Office of Clinical Evaluation & Policy, stated that the decision "[w]as not sitting well with me at all," and wanted it escalated "to ensure that the rebate gain outweighs the likely erosion of our reputation." Nancy Pehl, Senior Director, Drug Evaluation Unit Office of Clinical Evaluation & Policy at Express

¹⁰⁶ *Id.* at 2-6.

¹⁰⁷ *Id.* at 8-14.

Scripts, responded the same day that the decision "is really sad, really disheartening" and made "[n]o clinical sense to say the least." ¹⁰⁸

381. For years, Express Scripts' executives observed that efforts to address opioid overutilization with respect to Medicare were not being offered or implemented on the commercial side. In 2014, Snezana Mahon and Amanda Dwyer commented about the fact that "what is available in Medicare is not fully available in Commercial." Ms. Mahon commented that Express Scripts knew that it scored poorly in these areas and have been filling out response to an RFP for the last couple years to that effect. In response, Amanda Dwyer commented that it is "unfortunate that what is available in Medicare is not fully available in Commercial, and [Express Scripts] continue[s] to just be okay with lacking in these areas." Ms. Mahon echoed these comments in 2016 during Express Scripts' "Opioid Summit" in discussing what Express Scripts needed to do to address inappropriate opioid utilization, stating, "CMS put in requirements that were [opioid] solutions that were not put into commercial because we didn't invest in the other lines of business."

- 382. In sum, in exchange for lucrative financial benefits from the opioid manufacturers, Express Scripts have stoked the fires of the opioid epidemic by allowing unfettered access on their standard formularies to dangerous, highly addictive opioids with minimal, if any, restrictions.
- 383. That reality, however, has not deterred PBMs from publicly touting their unique ability to alter the course of the opioid epidemic.

¹⁰⁸ ESI JEFFCOMO 000029940 (3/23/17).

¹⁰⁹ ESI_JEFFCOMO_000095166.

 $^{^{110}}$ *Id*.

¹¹¹ ESI JEFFCOMO 000109001.

384. On February 18, 2018, Snezana Mahon, Express Scripts Vice President of Clinical Product Development, testified before the United States Senate Committee on Health, Education, Labor and Pensions hearing titled, "The Opioid Crisis: The Role of Technology and Data in Preventing and Treating Addiction." During the hearing, Ms. Mahon testified about out how Express Scripts had the ability to "minimize early opioid exposure and prevent progression to overuse and abuse." Ms. Mahon further testified to Congress:

Because Express Scripts interacts with patients, pharmacies, prescribers, and payers, our company is uniquely situated to collect data when patients receive and fill a prescription for an opioid under their pharmacy benefit. We can leverage that data across the care continuum in order to design interventions aimed at preventing opioid addiction from beginning in the first place. With 2 million Americans addicted to prescription narcotics, and more than 1,000 people treated daily in emergency departments for misusing prescription opioids, this is a \$53 billion public health crisis. 112

385. Despite having been "uniquely positioned" to change the trajectory of the opioid epidemic, Express Scripts instead sat "idly by" for years. Even when it finally began to take some steps to ostensibly address the crisis, Express Scripts recognized that these measures were ineffective. For example, a July 2016 internal ESI memorandum about the upcoming "Opioid Summit" indicated that while ESI had "several tools and solutions to identify and manage opioids ... our solutions are sometimes disjointed and lack coordinated approaches." Similarly, a 2017 presentation described ESI's existing opioid solutions as "fragmented," "disjointed" and having "no clear value prop."

¹¹² Snezana Mahon, PharmD, *The Opioid Crisis: The Role of Technology and Data in Preventing and Treating* Addiction (February 27, 2018), https://www.help.senate.gov/imo/media/doc/Mahon.pdf (emphasis added).

¹¹³ ESI JEFFCOMO 000028723 (7/4/16).

¹¹⁴ ESI JEFFCOMO 000179506 (3/31/17).

- b. Express Scripts chose not to use its "Drug Utilization Review" tools to address overprescribing, abuse and diversion.
- 386. Express Scripts also had its Drug Utilization Review ("DUR") programs available to control the flow of opioids, but chose not to use this tool either. Internal documents from Express Scripts show that rebate monies had a direct impact on how Express Scripts managed access to prescription opioids, including their obligations to monitor on a real-time basis through concurrent drug utilization review that only safe and appropriate opioid prescriptions would be filled.
- 387. "Concurrent DUR" or "cDUR" involves the real-time evaluation of drug therapy and intervention, if necessary, while the patient is undergoing therapy, including screening at the point of sale for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse.
- 388. But they refused to use cDUR to control opioid misuse because doing so would have impacted their revenue, including receipt of rebates, income generated from opioid dispensing, and other fees. For years, Express Scripts failed to deploy cDUR initiatives to ensure that only appropriate opioid prescriptions were being dispensed in pharmacies across the country (including in their own mail order pharmacies). This intentional refusal by Express Scripts permitted the dramatic increase in medically inappropriate prescribing and dispensing of prescription opioids that contributed to the fueling of the opioid epidemic.
- 389. Even when some clients attempted to place cDUR dosage limits on excessive use of opioids, Express Scripts colluded with the prescription opioid manufacturers to push back.
- 390. Even when the FDA in 2013 removed the indication for use of long-acting narcotics to treat moderate pain, Express Scripts saw no reason to change its cDUR program, acknowledging

that its strategy was "more focused on driving preferred products and managing quantities." One ESI employee at the time described the FDA change as "kind of a non-event." ¹¹⁶

- 391. Several years later, in 2016 when ESI tried to implement cDUR limits on Purdue's drugs, the manufacturer pushed back, reminding ESI that the cDUR limits (which would have restricted opioid use to acute pain, blocked opioids unless the use was for cancer or other approved uses, or required prior authorization for all opioids) would be in violation of its rebate agreement.
 - c. Express Scripts failed to use its vast stores of data, its formulary and UM offerings, and its DURs to provide effective controls against diversion and/or to prevent the diversion and abuse of prescription opioids.
- 392. Express Scripts was uniquely situated to protect against the abuse and diversion of opioids, but as described above, chose not to do so.
- 393. Express Scripts used different corporate entities to operate its PBM and mail-order dispensing businesses. But Express Scripts knew that prescription opioids presented serious risks of abuse and diversion and knew that its mail-order pharmacy was required by the CSA to provide effective controls against diversion. Express Scripts also knew that it was in possession of massive amounts of data that could be used to provide such effective controls, and also knew that they had a panoply of tools at its disposal—standard formularies, UM tools, and DUR programs—all of which could be used to reduce diversion. Even if the Express Scripts entities that provide PBM services are not themselves subject to DEA oversight, those entities had parallel responsibilities to operate their PBM services with appropriate care in light of the dangers of diversion that the CSA is designed to guard against. Any controls that Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy, Inc. and Express Scripts Specialty Distribution Services, Inc. (all DEA registrants)

¹¹⁵ ESI JEFFCOMO_000169781 (9/11/13).

¹¹⁶ *Id*.

provided (assuming there were any) could not be effective while its sister companies conducted their PBM activities so as to maximize the volume of opioid sales. Either way, Express Scripts had a duty to operate its PBM business in such a way as to minimize or reduce the risks that these dangerous drugs would be diverted. All of the data available to Express Scripts was also available to its mail-order dispensing affiliates, and those entities had a duty to use that data in maintaining effective controls against diversion, but they failed to do so.

- E. For Nearly Two Decades After It Knew Opioids Were Causing a Public Health Crisis, Express Scripts Finally Implemented Protocols to Address the Opioid **Epidemic**
- After decades of working to increase opioid utilization, in 2017, due to mounting pressure from their clients and the federal government, Express Scripts finally implemented programs aimed at addressing opioid overutilization and abuse. Express Scripts' Advanced Opioid Management ("AOM") program started on September 1, 2017.
- 395. As discussed above, Express Scripts undoubtedly had knowledge of the opioid crisis years, if not two decades, earlier.
- 396. Moreover, for years prior to actually implementing these programs, Express Scripts publicly touted its ability to translate the incredible amount of data it received into solutions to address pressing problems in healthcare. For example, in 2013 Forbes article titled "How Express Scripts Uses Analytics to Improve Patient Outcomes," Express Scripts Chief Information Officer, Gary Wimberly stated, "By filling 1.4 billion prescriptions per year, we have over 10 petabytes of useful data from which we can gain insights and for which we can develop solutions."117
 - 397. Express Scripts' client-facing presentations echoed Mr. Wimberly's statements:

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¹¹⁷ Stacy Dep. Ex. 8.



- 398. Yet, despite having access to petabytes of data for over a decade prior to rolling out the AOM (as discussed above) showing opioid overutilization and despite Express Scripts publicly promoting itself as a bastion of public health for years, the AOM program did not roll out to plan sponsors until 2017, at which point plans had to "buy up" to receive the program. Said another way, Express Scripts did not act for nearly *17 years after* it was aware of the prescription drug opioid crisis and not until after Express Scripts received an investigation inquiry from the United States Senates related to opioid overutilization and the CDC declared that addiction could occur between five days and one month.
- 399. As debuted on September 1, 2017, Express Scripts' AOM 1.0 program finally provided tools (such as prior authorizations) at the pharmacy level (referred to as "point of sale" or "POS") that Express Scripts should have been offering for decades prior. Notably, the AOM

program was the first time ESI had taken any direct steps to limit the quantity or flow of short acting opioids. AOM's new POS rules included the following:

- (a) 200 MME cumulative per day limit for opioid Rx's;
- (b) Above 200 MME requires a prior authorization (PA); and
- (c) Pharmacist is alerted at 90 MME.
- 400. The limits were "cumulative" across all opioid medications prescribed to the patient/member and limiting opioid naïve patients to 7-day supply for short acting opioid (SAO) prescriptions. Further, the Enhanced Prior Approval applied across all Long-Acting Opioids (LAO), whether generic or brand. In addition, a new patient required first fill of a short acting opioid before using a long-acting opioid. AOM also included non-utilization management elements such as proactive member education (letter after first fill), Opioid Disposal Bags, and Physician care alerts (messaging via EMR on MED and other issues).
- 401. Express Scripts stated that its AOM program was "designed to align with the [2016] Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain." The program, however, did not align with the 2016 CDC Guidelines and in fact the featured limits were excessive and dangerous when compared to the CDC Guidelines. Nonetheless, Express Scripts claimed the following successes in first six months of the program:
 - (a) 59.5% reduction in average days' supply of opioids for first time users;
 - (b) 95.9% of prescriptions that were reprocessed because of UM edits were filled for 7-day supply or less;
 - (c) only 4.1% of prescriptions were filled for more than 7 days after prior authorization process was complete; and

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¹¹⁸ Blair Dep. Ex. 21.

- (d) 87% of new opioid prescriptions written for an LAO were subsequently filled with an SAO due to new enhanced PA program. 119
- 402. As of September 2019, two years after the initial AOM rollout, Express Scripts claimed the following successes:
 - (a) 1.4 million fewer days' supply of opioids have been dispensed, while directing patients to safer, short-acting alternatives; 120
 - (b) 40.6% reduction in average MME for new opioid users;
 - (c) 77% of patients prescribed an LAO as initial therapy were redirected to an SAO; and
 - (d) 95.8% "success rate" of new members being dispensed an opioid claim at or below 90 MME. 121
- 403. Subsequent AOM enhancements added new limits on fentanyl products and opioid adjacent therapy quantity limits, as well as:
 - (a) "Initial fill days' supply rule for adults initiating opioid therapy limited to a 7-days' supply for members' first 4 fills, requiring a prior authorization to exceed 28-days' supply in a 60-day period;" 122 and
 - (b) "[L]imiting the morphine equivalent dosing to 90 MME for patients starting on opioids. Existing users are limited to 200 MME, unless they receive a prior authorization for a higher dosage." 123
 - 404. By 2019, 17.4 million Express Scripts covered lives were enrolled in the AOM.
- 405. Notably, Express Scripts could have implemented these opioid reducing measures at any point over the past two decades as it tracked the opioid epidemic unfolding across the

¹¹⁹ Stettin Dep. Ex. 5.

¹²⁰ Express Scripts, 17.4 Million Americans Protected from a Nationwide Health Crisis, https://www.express-scripts.com/corporate/solutions/improving-health#advanced-opioid-management (last accessed Nov. 14, 2023).

¹²¹ Stettin Dep. Ex 12.

¹²² Blair Dep. Ex. 21.

 $^{^{123}}$ *Id*.

country. Quantity limits and prior authorizations have been used to control drug utilization since before Express Scripts was a PBM. And Express Scripts has been using step therapy since the late 1990s.

406. Yet, Express Scripts failed to implement its opioid programs for over a decade after their own reports, studies, and clients were alerting them to the need for an "aggressive" policy to address "rampant abuse and inappropriate" opioid use. Had Express Scripts created effective protocols to address the opioid overutilization—such as those implemented in 2017—when it first knew these drugs were causing a public health crisis—it could have significantly reduced the amount of opioids dispensed throughout the country, including in Plaintiffs' Communities, and reduced the harm caused by the opioid epidemic.

VII. As A Mail Order Pharmacy, Express Scripts Dispensed Opioids in Violation of the Controlled Substances Act, West Virginia law and the West Virginia Controlled Substances Act.

A. The Applicable Statutes

407. In March 2016, the CDC, in order to reduce opioid addiction, overdoses, and deaths, published specific recommendations for clinicians who prescribe opioids outside of cancer treatment, palliative care, and end-of-life care. The CDC recommendations are based on "[s]cientific research [that] has identified high-risk prescribing practices that have contributed to the overdose epidemic (*e.g.*, high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting opioids for acute pain)."¹²⁴

¹²⁴ OPTUMRX JEFFCO 0000604271 at 3.

408. Congress has found that pharmacies share responsibility for the crisis: "The opioid epidemic . . . has arisen, in part, from the diversion of prescription opioids through illegal dispensing practices at pharmacies." ¹²⁵

409. Express Scripts knowingly violated it duties under the federal Controlled Substances Act ("CSA") and its implementing regulations, the West Virginia Controlled Substances Act ("WVCSA") and its implementing regulations, including but not limited to 21 U.S.C.A. §§ 829, 841 842; 21 C.F.R. §§ 1301.71, 1306.04, 1306.06; W. Va. C.S.R. § 15-2-3 (previously W.Va. C.S.R. § 15-2-2), W. Va. C.S.R. § 15- 2-4, W.Va. C.S.R. § 15-2-4.4, W.Va. C.S.R. § 15-2-4.5, W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1), W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4), W.Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); and W. Va. Code § 60A-3-308(d)(1), ignoring their obligation to provide effective controls against diversion.

1. The Controlled Substances Act and the West Virginia Controlled Substances Act

410. The CSA and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to

¹²⁵ U.S. Senate Homeland Sec. & Governmental Aff. Comm., Ranking Member's Off., Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement, at p. 4 (July 12, 2017) https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/REPORT-Fueling%20an%20Epidemic-

A%20 Flood%20 of%201.6%20 Billion%20 Doses%20 of%20 Opioids%20 into%20 Missouri%20 and%20 the%20 Need%20 for%20 Stronger%20 DEA%20 Enforcement.pdf.

manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 126

- 411. The CSA categorizes controlled substances in five "Schedules."
- 412. Schedule II (also called herein CII) contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence," but nonetheless have "a currently accepted medical use in treatment." ¹²⁷
- 413. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have "a currently accepted medical use." ¹²⁸
- 414. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused. 129
- 415. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused. 130
- 416. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized.¹³¹
- 417. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA.¹³² A registrant is only permitted to

¹²⁶ See 21 U.S.C. § 841(a).

¹²⁷ 21 U.S.C. § 812(b)(2).

¹²⁸ 21 U.S.C. § 812(b)(3).

¹²⁹ 21 U.S.C. § 812(b)(4).

¹³⁰ 21 U.S.C. § 812(b)(5).

¹³¹ 21 U.S.C. § 841(a)(1).

¹³² 21 U.S.C. § 822(a).

dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with the [CSA]." ¹³³

- 418. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA.¹³⁴
- 419. At all times relevant to this Complaint, Express Scripts registered its mail order pharmacies with the DEA in Schedule II–V controlled substances. Those DEA registrations authorize Express Scripts'-owned pharmacies to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user ... by, or pursuant to the lawful order of, a practitioner." ¹³⁵
- 420. In the case of Express Scripts, the entities that are registered with the DEA are Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy, Inc. and Express Scripts Specialty Distribution Services, Inc.
- 421. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered mail order pharmacy like those owned by Express Scripts, are not required to register with the DEA "if such agent or employee is acting in the usual course of his business or employment." ¹³⁶
- 422. Under the CSA, the lawful dispensing of controlled substances is governed by 28 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations. ¹³⁷

¹³³ 21 U.S.C. § 822(b).

¹³⁴ 21 U.S.C. § 829.

¹³⁵ 21 U.S.C. § 802(10), accord 21 U.S.C. § 823(f).

¹³⁶ 21 U.S.C. § 822(c)(1).

¹³⁷ See generally 21 C.F.R. § 1306.

423. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency.¹³⁸ Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner.¹³⁹

424. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA.¹⁴⁰

425. A prescription, whether written or oral, is legally valid under the CSA *only* if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." ¹⁴¹ Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." ¹⁴²

426. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

¹³⁸ 21 U.S.C. § 829(a).

¹³⁹ 21 U.S.C. § 829(b).

¹⁴⁰ 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

¹⁴¹ 21 C.F.R. § 1306.04(a).

 $^{^{142}}$ *Id*.

 $^{^{143}}$ *Id*.

- 427. Moreover, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually, or employed in a registered pharmacy...."
- 428. Pharmacists are therefore permitted to dispense a controlled substance in any given instance if, *but only if*, such dispensing would be in accordance with a generally accepted, objective standard of practice—*i.e.*, "the usual course of his [or her] professional practice" of pharmacy.¹⁴⁵
- 429. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose.¹⁴⁶
- 430. Unlawful dispensing of controlled substances by a pharmacist may subject the pharmacy or pharmacist to criminal actions and to civil enforcement actions for money penalties or injunctions.¹⁴⁷
- 431. A pharmacy also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. He pharmacist has a legal duty to recognize "red flags" or warning signs that raise (or should raise) a reasonable suspicion that a prescription for a controlled substance is not legitimate. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing. A pharmacist's corresponding responsibility extends to the pharmacy itself.

¹⁴⁴ 21 C.F.R. § 1306.06.

 $^{^{145}}$ Id.

¹⁴⁶ See 21 C.F.R. §§ 1306.04, 1306.06.

¹⁴⁷ 21 U.S.C. §§ 842, 843.

¹⁴⁸ United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (Rev. 2020).

- 432. A pharmacy's registration can be revoked because its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of further discipline.¹⁴⁹
- 433. In addition to the CSA, Express Scripts was also required to comply with West Virginia controlled substances law and pharmacy regulations, including, but not limited to, the West Virginia Controlled Substances Act, W. Va. C.S.R. § 15-2-3 (previously W.Va. C.S.R. § 15-2-2), W. Va. C.S.R. § 15- 2-4, W.Va. C.S.R. § 15-2-4.4, W.Va. C.S.R. § 15-2-4.5, W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1), W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-4.4), W. Va. Code § 60A-4-401(a), W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); and W. Va. Code § 60A-3-308(d)(1).
- 434. The Rules of the West Virginia Board of Pharmacy for the West Virginia Uniform Controlled Substances Act are codified in W.Va. C.S.R. § 15-2-1, *et seq*.
- 435. The West Virginia Uniform Controlled Substance Act requires "every person who manufactures, distributes, or dispenses any controlled substance within this state" to "obtain annually a registration issued by the state board of pharmacy." W. Va. Code § 60A-3-302(a); see also W.Va. C.S.R. § 15-2-4 (previously W.Va. C.S.R. § 15-2-3).
- 436. Express Scripts is registrant and has a duty to comply with federal, state, and local laws regarding the distribution of drugs. W. Va. Code § 60A-8-7(c)(1)(I); see also W. Va. Code §

¹⁴⁹ United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (Rev. 2020) (citing *Jones Total Healthcare, L.L.C., v. DEA*, 881 F.3d 823 (11th Cir. 2018)).

- 60A- 8-7(c)(3) (requiring compliance with guidelines adopted by the United States Food and Drug Administration).
- 437. The West Virginia Board of Pharmacy has adopted, by reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. W. Va. C.S.R. § 15-2-3 (previously W. Va. C.S.R. § 15-2-2).
- 438. West Virginia state law expressly imposes a duty upon Express Scripts to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).
- 439. Express Scripts had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).
- 440. West Virginia state law further imposes a duty upon Express Scripts to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered "by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders." W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4). Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Id.
- 441. Express Scripts had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity. See 21 U.S.C. §823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4).

- 442. Federal and West Virginia laws and regulations require Express Scripts to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. See 21 U.S.C. § 823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4).
- 443. The WVCSA further prohibits any person "[w]ho is subject to article 3 to distribute or dispense a controlled substance in violation of section [60A-3-]308." W. Va. Code § 60A-4-402(a)(l). Section 60A-3-308 of the WVCSA governs distribution of controlled substances, which is prohibited except by prescription. It provides, for example, that substances included in certain schedules of the law "shall not be distributed or dispensed other than for a medicinal purpose." W. Va. Code § 60A-3-308(d)(l).
- 444. Express Scripts failed to meet it duties and obligations under federal and West Viginia law and violated the applicable standard of care.

2. Pharmacies Like Express Scripts Are Obligated Not to Fill Prescriptions Until All Red Flags Are Resolved.

445. A pharmacy cannot ignore red flags indicative of abuse and diversion. On the contrary, "a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose." [W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions." Thus, § 1306.064 requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors

¹⁵⁰ Medic-Aid Pharmacy, Revocation of Registration, 55 Fed. Reg. 30,043-01, 30,044, 1990 WL 328750 (Dep't of Just. July 24, 1990).

¹⁵¹ East Main Street Pharmacy, Affirmance of Suspension Order, 75 Fed. Reg. 66,149-01, 66,150, 2010 WL 4218766 (Dep't of Just. Oct. 27, 2010).

writing prescriptions and whether the drugs prescribed have a high rate of abuse or diversion. ¹⁵² "When [pharmacists'] suspicions are aroused as reasonable professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense." ¹⁵³

flags are resolved. ¹⁵⁴ In *Medicine Shoppe-Jonesborough*, the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated § 829 of the CSA and 21 C.F.R. § 1306.04. The Court held "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)." Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe." By filling these

¹⁵² Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, Inc., Revocation of Registration, 55 Fed. Reg. 4,729-01, 4,730, 1990 WL 352775 (Dep't of Just. Feb. 9, 1990).

¹⁵³ Id.; see also Townwood Pharmacy, Revocation of Registration, 63 Fed. Reg. 8,477-04, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998); Grider Drug No. 1 & Grider Drug No. 2, Decision & Order, 77 Fed. Reg. 44,070-01, 2012 WL 3027634 (Dep't of Justice July 26, 2012); The Medicine Dropper, Revocation of Registration 76 Fed. Reg. 20,039-01, 2011 WL 1343276 (Dep't of Justice Apr. 11, 2011); Medicine Shoppe-Jonesborough, Revocation of Registration, 73 Fed. Reg. 364-01, 2008 WL 34619 (Dep't of Justice Jan. 2, 2008); United Prescriptions Services, Inc., Revocation of Registration, 72 Fed. Reg. 50,397- 01, 50,407-8, 2007 WL 2455578 (Dep't of Just. Aug. 31, 2007).

See Med. Shoppe-Jonesborough v. Drug Enf't Admin., 300 F. App'x 409, 413-14 (6th Cir. 2008); United States v. Henry, 727 F.2d 1373, 1378-79 (5th Cir. 1984); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145, 160 (D.D.C. 2012).

¹⁵⁵ Med. Shoppe-Jonesborough, 300 F. App'x at 412.

¹⁵⁶ *Id*. at 413.

prescriptions anyway. . . the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk."¹⁵⁷

- 447. The MDL Court has addressed this very issue. The Court unequivocally stated that "[t]here is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances." ¹⁵⁸
- 448. In fact, the MDL Court found that the corporate parents of chain pharmacies have an affirmative obligation under the CSA to "design and implement systems, policies, or procedures to identify red flag prescriptions." The Court reasoned that pharmacies "cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually facilitate diversion, and thus violate the CSA's fundamental mandate that '[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a) (emphasis added)."

 $^{^{157}}$ *Id*.

¹⁵⁸ In re Nat'l Prescription Opiate Litig., 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020), clarified on denial of reconsideration, No. 1:17-MD-2804, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020). See also City and Cnty. Of San Francisco v. Purdue Pharma L.P., 620 F. Supp. 3d 936, 960 (N.D. Cal. 2022).

¹⁵⁹ In re Nat'l Prescription Opiate Litig., 477 F. Supp. at 630.

¹⁶⁰ *Id*.

3. The CSA and West Virginia Controlled Substances Act Apply to All Persons Who Dispense Controlled Substances Like Express Scripts.

449. Courts have found that because the plain language of § 842 extends its requirements to "all persons," registrants and non-registrants alike are responsible for complying with the law. 161 Importantly, in those cases, the courts found that because the pharmacy owners, who were not registrants, essentially operated the facilities on a day-to-day basis, they were not exempted from the requirements of Section 842. 162

450. At least one court has explicitly held that a non-registrant pharmacy owner can be held liable for dispensing controlled substances without valid prescriptions. In *United States v. City Pharmacy*, the court found that the owner of the pharmacy could be held liable in his personal capacity for violations of Section 842(a)(1) even though he was not a registrant and the pharmacies he owned were separately incorporated. The United States brought an action alleging that City Pharmacy LLC and City Pharmacy of Charles Town, Inc. violated Section 842(a)(1) by filling illegitimate prescriptions for controlled substances that raised one or more red flags, such as customers traveling long distances or customer receiving drug cocktails. 164

¹⁶¹ See United States v. Blanton, 730 F.2d 1425, 1434 (11th Cir. 1984) (Section 842(a)(5) applied to a physician who was not properly registered with the DEA); United States v. Clinical Leasing Serv., Inc., 759 F. Supp. 310, 313-14 (E.D. La. 1990), aff'd, 925 F.2d 120 (5th Cir. 1991) ("Had Congress intended to limit the applicability of § 842(a)(5) to registrants only, it would have done so"); United States v. Stidham, 938 F. Supp. 808, 814 (S.D. Ala. 1996); United States v. Poulin, 926 F. Supp. 246, 250, 253 (D. Mass. 1996).

¹⁶² Stidman, 938 F. Supp. at 809, 814 (the owner of a clinic, who was not a registrant, could be liable because he "shouldered [the] responsibility [to provide a system for the control of drug traffic and to prevent the abuse of drugs] and derived the benefits and profits from operating a methadone clinic."); *Poulin*, 926 F. Supp. at 249, 253 ("Although Mattapoisett Pharmacy, Inc. was listed as the registrant, the statute specifically makes the stated obligations to produce required records applicable to all persons, not simply to registrants.").

¹⁶³ United States v. City Pharmacy, LLC, No. 3:16-CV-24, 2016 WL 9045859, at *4 (N.D. W.Va. Dec. 19, 2016).

¹⁶⁴ *Id*. at *1.

451. The court held that Section "842(a)(1) applies to non-registrants." The court continued, explaining that "because part C of the CSA applies broadly to all persons involved in the manufacture, distribution, and dispensing of controlled substances, including lay-persons, defendant Lewis may potentially be held liable for his conduct." To support its conclusion, the court concentrated on defendant Lewis' involvement with the pharmacies at issue, looking specifically at his investment of the funds to organize and open the pharmacy, the active role he played in the management of the pharmacies, including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

452. The *City Pharmacy* court also found that the individual defendant could not use the pharmacies' separate incorporation to shield himself from CSA liability. Evaluating various legal mechanisms for piercing the corporate form, the court concluded that the pharmacies "were being used to evade the legal requirements within and undermine the public policy foundations of the CSA." Thus, the court held, "given the nature of these criminally-grounded allegations, it is not a defense to liability in this case for defendant Lewis to assert that he is shielded by the corporate form. [The pharmacies] were allegedly the entities used to evade and subvert the requirements of the CSA." 168

¹⁶⁵ Id. at *2 (citing United States v. Moore, 423 U.S. 122, 134 n.11 (1975) and United States v. Stidham, 938 F. Supp. 808, 813-814 (S.D. Ala. 1996)).

¹⁶⁶ *Id*. at *3.

¹⁶⁷ *Id*. at *4.

¹⁶⁸ Id.; see also Poulin, 926 F. Supp. at 253 ("Mattapoisett Pharmacy, Inc. is also the alter ego of its sole owner, David Poulin, and thus David Poulin cannot use the corporate name to shield himself from personal liability."); S & S Pharmacy, Denial of Registration, 46 Fed. Reg. 13,051-03, 13,052, 1981 WL 96125 (Dep't of Justice Feb. 19, 1981) ("[T]he Administrator has in the past looked behind the corporate-veil to revoke or deny a registration when a responsible official of a corporate registrant has been convicted of violating the laws relating to controlled substances."); United States v. Robinson, No. 12-

453. Just like the defendant in *City Pharmacy*, as alleged more fully herein, Express Scripts has invested the funds to organize and open their mail order pharmacies and play a very active role in the management of those pharmacies, including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

B. Express Scripts Violated the Controlled Substances Act, West Virginia law, and the West Virginia Controlled Substances Act.

- 454. At all times material hereto, DEA registrants like Express Scripts had the duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances." Diversion includes the use of medication outside the usual course of professional practice.
- 455. The DEA has repeatedly emphasized that, as DEA registrants, pharmacies like those owned and controlled by Express Scripts are required to implement systems that will detect and prevent abuse and diversion and must monitor for red flags of abuse and diversion. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against

²⁰³¹⁹⁻CIV, 2012 WL 3984786, at *7 (S.D. Fla. Sept. 11, 2012), (finding a non-registrant owner of a pharmacy could be held liable for violations of Section 842 because the defendant was "alleged to have had responsibility over the controlled substances" and holding that "[w]here corporate officers have been in a position to prevent or correct the violations at issue, courts have found that there is individual liability under the [Section 842], which plainly applies to all 'persons."); *United States v. Ahmad*, No. 4:15CV-181-JM, 2016 WL 11645908, at *3 (E.D. Ark. May 2, 2016), *aff'd sub nom. United States v. United Pain Care, Ltd.*, 747 F. App'x 439 (8th Cir. 2019) (an owner receiving the "benefits and profit" of a pharmacy, but who was not a registrant or a medical professional, can be liable for violations of the CSA because he was still "responsible for making sure that [CSA] requirements were met.").

¹⁶⁹ 21 C.F.R. § 1301.71(a).

abuse and diversion in regulatory action after regulatory action. ¹⁷⁰ According to the DEA, pharmacists are the "[l]ast line of defense." ¹⁷¹

- 456. The framework of state and federal statutes and regulations, along with industry guidelines, make clear that pharmacies like those Express Scripts owns are expected to use specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the abuse and diversion of prescription narcotics when dispensing of medications outside the usual course of professional practice.
- 457. Express Scripts was on notice that case law and administrative proceedings interpreting the CSA clearly required that their pharmacies must recognize and resolve all "red flags" indicating addiction, abuse and diversion, such as criminal, civil, or administrative actions pending against the prescriber, pattern prescribing, pharmacy shopping, doctor shipping, high abuse potential prescriptions, drug cocktails, *etc.* ¹⁷²

¹⁷⁰ See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, Decision & Order, 77 Fed. Reg. 62,316-01, 2012 WL 4832770 (Dep't of Justice Oct. 12, 2012); East Main Street Pharmacy, Affirmance of Suspension Order, 75 Fed. Reg. 66,149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010); Holiday CVS, L.L.C. v. Holder, 839 F. Supp. 2d 145 (D.D.C. 2012); Townwood Pharmacy, Revocation of Registration, 63 Fed. Reg. 8,477-04, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998); Grider Drug No. 1 & Grider Drug No. 2, Decision & Order 77 Fed. Reg. 44,070-01 (Dep't of Justice July 26, 2012); The Medicine Dropper, Revocation of Registration, 76 Fed. Reg. 20,039-01 (Dep't of Justice Apr. 11, 2011); Medicine Shoppe-Jonesborough, Revocation of Registration 73 Fed. Reg. 363-01 (Dep't of Justice Jan. 2, 2008).

¹⁷¹ See Thomas W. Prevoznik, Birmingham Pharmacy Diversion Awareness Conference, DEA Perspective: Pharmaceutical Use & Abuse, at 139-40 (Mar. 28-29, 2015), https://web.archive.org/web/20160418074249/https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf.

Holiday v. Holder, 839 F. Supp. 2d 145; Pharmacy Drs. Enterprises, Inc. v. Drug Enf't Admin., 789 Fed. App'x 724, 730 (11th Cir. 2019); Holiday CVS, 77 Fed. Reg. at 62,318, 62,326, 62,331, 62,344; East Main Street Pharmacy, 75 Fed. Reg. at 66,159; Oak Hill Hometown Pharmacy v Dhillon, 418 F. Supp. 3d. 124, 131 (S.D. W. Va., 2019); Jones Total

458. It is not just the single red flags that make the suspicious prescriptions unresolvable, but frequently the fact that there are multiple red flags at one time. So, rather than just looking for unresolvable single red flags, Express Scripts should have been looking for instances when there are multiple red flags in combination, which would make these truly unresolvable. According to *Holiday CVS*:

Professor Doering specifically identified such red flags as. . . ; the respective locations of the patient and the prescriber . . . ; that a prescriber writes for certain combinations or patterns of drugs. . . .; and multiple patients presenting "prescriptions for the same drugs, the same quantities . . . from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy," thus suggesting that the physician prescribes in a "factory like manner." *Id.* Professor Doering reviewed the various spreadsheets of the prescriptions dispensed by Respondents and testified regarding whether Respondents could have lawfully dispensed various prescriptions given the red flags they presented.¹⁷³

459. Nor would Express Scripts be able to dispense a prescription with multiple red flags by simply making a call to the prescriber. According to *Holiday CVS*:

Doering explained that the pharmacist examines multiple red flags collectively, and testified that, in his opinion, contacting the prescribing physician and/or obtaining a diagnosis code would not resolve these red flags to a degree where the medications should have been dispensed. Tr. 792–93. Doering agreed that he did not know what measures, if any, the Respondents' pharmacists took to resolve any conflicts, or whether a patient history screen was consulted prior to the dispensing event. Tr. 868, 873. When pressed on whether the distance red flags were potentially explainable under various hypothetical scenarios involving vacation and travel,

Health Care Pharmacy, LLC v. DEA, 881 F.3d 823, 828 (11th Cir. 2018); "Centers for Disease Control, CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," Morb. Wkly. 65 and Mort. Rep. (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf; Seesupra, Prevoznik, Birmingham Pharmacy Diversion AwarenessConference. 139-140. https://web.archive.org/web/20160418074249/https://www.deadiversion.usdoj.gov/mtgs/ph arm awareness/conf 2015/march 2015/prevoznik.pdf.

¹⁷³ *Holiday CVS*, 77 Fed. Reg. at 62,318.

Doering had this to say: "The kinds of medications that we're talking about here are for chronic health problems and not acute health problems. So, it would be unlikely that someone comes to Florida on vacation, breaks a leg, and has to get oxycodone in these quantities and in these strengths. So it just doesn't add up." 174

- 460. At all times material hereto, Express Scripts has been in the position to recognize those red flags listed above. Upon information and belief, all or some of those red flags were frequently present in hundreds of thousands of prescriptions its pharmacies received during the relevant time period and should have caused Express Scripts' mail order pharmacies to refuse to fill prescriptions and/or report the behavior. However, Express Scripts failed to do so.
- 461. Express Scripts, as a sophisticated owner of multiple mail order pharmacies, had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Express Scripts tracks every prescription claim it processes across all the health plans it services. Furthermore, Express Scripts could aggregate these data across various entities in the pharmaceutical supply chain, including drug manufacturer, pharmacies, insurers, and patients. Its own data would have allowed Express Scripts to observe patterns or instances of dispensing that are potentially suspicious of diversion or oversupply in particular stores or geographic areas, and of prescribers or facilities that seem to engage in improper prescribing.¹⁷⁵
- 462. Rather than use their data to limit problematic opioid utilization or investigate outlier prescribers, Express Scripts sold the data to third-party vendors who in turn resold the data to drug makers like Purdue Pharmaceuticals. Drug makers used these data to stoke increased sales of opioid drugs to physicians throughout America to treat the "fifth vital sign"—requiring

¹⁷⁴ *Id.* at 62,334.

¹⁷⁵ See, e.g., id., at 62,326-28 (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

healthcare providers to ask every patient about their pain, given the perception at the time that pain was undertreated. Since that time, the U.S. has experienced a surge in opioid prescriptions—and, subsequently, an increase in overdoses and deaths tied to these painkillers.¹⁷⁶

- 463. Yet, Express Scripts did little to leverage its resources and troves of information to stop or further question the wildly inappropriate prescriptions being written by prescribers until well after the opioid epidemic had reached its peak.
- 464. Express Scripts did little to fulfill its duties as the last line of defense and failed to ensure that the prescriptions they were filling were issued to legitimate patients for legitimate medical purposes by practitioners acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed by Express Scripts' mail order pharmacies throughout the United States including West Virginia, Plaintiffs' Communities, and this Judicial District.
- 465. The absence of controls against diversion is not surprising, given how Express Scripts' mail-order pharmacies operated to push virtually all prescriptions out the door, with little or no attempts at identifying or resolving red flags. The pressure on its pharmacists to fill large volumes of prescription made the performance of appropriate due diligence difficult, if not impossible.
- 466. For instance, employees at Express Scripts mail order pharmacies routinely complained of being under significant pressure to fill as many prescriptions as possible in as short amount of time as possible. In this vein, Express Scripts instituted a "point system" that governed

¹⁷⁶ Kristina Fiore, "Opioid Crisis: Scrap Pain as 5th Vital Sign? — Groups call on JC and CMS to re-evaluate policies that could lead to opioid overprescribing," *MedPage Today* (Apr. 31, 2016), https://www.medpagetoday.com/publichealth/57336 [https://web.archive.org/web/20160415143337/https://www.medpagetoday.com/publichealth/57336]

the prescription-filling process in its mail order facilities. Under the point system, employees were awarded points for each prescription processed, and were given daily, weekly, or monthly point targets to reach. Employees would be able to leave early if a daily point threshold was reached and were penalized if specific point targets were not reached. Continuous point shortfalls would result in employees being placed on a "termination plan" or resulted in receiving other types of reprimands, up to and including termination.

- 467. This point system has acted as a carrot and stick for Express Scripts' pharmacists and technicians to fill as many opioid prescriptions as possible in as little time as possible, despite legal requirements to properly and adequately identify and resolve red flags.
- 468. Activities such as placing calls to physicians or patients to verify prescription information were also strictly monitored for timing and efficiency, which came at the expense of meeting industry safety standards. For prescriptions that required phone calls to verify certain information, Express Scripts required employees to make and complete 12 calls per hour (or 1 call every 5 minutes) to meet certain point goals. Employees who engaged in calls that exceeded acceptable time limits were often berated or penalized by management. Employees expressed feeling extreme pressure to fill prescriptions at all costs, which reflected Express Scripts' goal of trying to fill everything it could as quickly as possible.
- 469. Given that Express Scripts' mail order dispensing policies prioritized speed and efficiency above all else, some employees reported complete mental and physical exhaustion, continuous fear of disciplinary action, and an unrelenting pressure to fill higher volumes of prescriptions in even shorter amounts of time.
- 470. Express Scripts' mail-order pharmacy entities were subject to DEA regulatory action for their failures to implement appropriate controls on dispensing. For instance, on May 15,

2012, Express Scripts Pharmacy Services, Inc. agreed to pay the United States \$2.75 million to resolve allegations under the Controlled Substance Act. Among the allegations was that from 2002 through 2006, drug diversion occurred at several Express Scripts mail order facilities, including facilities in Bensalem, PA and Harrisburg, PA. Express Scripts experienced theft by employees of controlled substances, had inventory discrepancies, and failed to report in-transit losses to the DEA. According to the DOJ press release, from 2004 through 2009, Express Scripts employees utilized invalid DEA numbers in Express Scripts' computerized prescription processing system in order to process certain controlled substances prescriptions at all of its mail order facilities.

- As part of the settlement, Express Scripts was required to develop a comprehensive Controlled Substances Security Compliance Plan that included diversion protection measures far beyond those required by law, including improved physical security, enhanced inventories, reconciliations and audits, employee background checks, and mandatory training for employees who have contact with controlled substances. Express Scripts executives, including the General Manager of Pharmacy Operations and the Chief Compliance Officer, were required to certify compliance with the terms of the Plan. In addition to the measures to protect against diversion of controlled substances, Express Scripts was also required to cease use of phony DEA numbers and agreed to set up an automated system to check the validity of prescribers' DEA and NPI (National Physician Identifier) numbers against a national registry.
- 472. In addition, as discussed above, starting in the 1990s and continuing for decades, Express Scripts and/or its subsidiaries (e.g. Express Scripts Specialty Distribution Services, Inc.; Express Scripts SDS; HealthBridge, United BioSource LLC; Curascript) also worked as the administrator (e.g. processing applications, patient enrollment, patient approval, handling appeals, tracking and analyzing program data, adverse event reporting, etc.) and/or mail order pharmacy

for manufacturers' opioid Patient Assistance Programs ("PAPs"), including for the troubled Purdue (Oxycontin, OxyIR) and Endo (Opana) PAPs. In connection with its PAP dispensing for Purdue and Endo, Express Scripts routinely violated the CSA by failing to ensure that only valid prescriptions were filled, failing to provide effective controls against diversion, and/or purporting to delegate its CSA responsibilities to the manufacturers funding the respective PAPs.

- 473. In connection with its opioid PAP and mail order dispensing and administration, Express Scripts routinely ignored clear indications of diversion, filled suspicious prescriptions, and/or improperly made opioid dispensing determinations at the direction of and/or with the inappropriate input/approval from the manufacturers funding the respective PAPs. The extent to which manufacturers controlled and/or had improper input into Express Scripts' dispensing practices is illustrated by the fact that the opioid PAP program created by Purdue and Express Scripts allowed a single patient to receive an astonishing 360 tablets of OxyContin and 3,000 tablets of OxyIR a month.
- 474. Express Scripts' administration and improper dispensing practices relative to Purdue's and Endo's PAPs helped make the respective programs very successful marketing tools to increase opioid use, drive volume, and facilitate access to opioids including OxyContin, Opana, as well as other opioid products resulting in Express Scripts filling 1 million+ opioid prescriptions and dispensing 100 million+ opioid pills throughout the country through these PAPs. As an illustration, in the early 2000s, Express Scripts was enrolling over 3,000 new patients per month for Purdue's PAP. Moreover, from at least the early 2000s, Express Scripts knew or should have known about the ongoing and growing misuse and diversion of opioids, and/or their opioid PAP work was causing opioid over-prescribing, over-dispensing, addiction and/or abuse, as well as the fact that it was a proximate cause of opioid diversion.

475. The Purdue and Endo PAPs and Express Scripts' administration and dispensing practices relative to same, raised numerous red flags, including dispensing large amounts of opioid to individuals, failing to conduct proper due diligence on patients, inappropriately recording deaths, and rerouting prescriptions to get around state laws.

476. For example, in 2010, Purdue audited Express Scripts' administration of this program and found numerous failures by Express Scripts to properly vet IPAP applicants, including failing to verify patient-doctor relationship, failing to notice obvious inconsistencies in applications, and failing to process IRS information to determine accuracy and legitimacy of the information. In fact, Purdue found that during a period of just a few months in 2010 Express Scripts dispensed more than 17,000 OxyContin pills to fraudulent PAP enrollees/applicants. Similarly, a 2010 email exchange between Purdue and Express Scripts employees outlined how a Purdue PAP patient was reportedly "selling [his PAP opioid prescriptions] on the street." 177

As a result of a whistleblower lawsuit brought by two former Las Vegas mail order pharmacists, in 2006 Medco agreed to a \$155 million settlement to resolve claims with the United States related to its dispensing of drugs at its mail order pharmacies. The government's complaint alleged Medco accepted payments from drug makers to favor their drugs and submitted false claims for mail order prescription drugs provided to millions of federal employees, retirees and their families. Among the allegations was that Medco's mail order pharmacies failed to conduct adequate cDUR for all prescriptions in order to identify potential adverse drug interactions. The government alleged that, as a result of the pressures to meet quotas, Medco's cDUR employees regularly: a) fabricated physician call records so as to maintain hourly call quota rates; b) completed physician calls without ever having pharmacists verify the information with the

¹⁷⁷ PPLPC034000383800.

physician's office; c) changed prescriptions without a pharmacist's intervention; and/or d) falsified records to indicate cDUR calls were made to physicians when in fact these calls had not been made.

- 478. At all times material hereto, Express Scripts' mail order pharmacies dispensed huge quantities of opioids, including into West Virginia, this District, and Plaintiffs' Communities. For example, during the 2006 to 2014 time period alone, Express Scripts pharmacies purchased approximately billions of MMEs units according to the DEA's Automated Reports and Consolidated Ordering System ("ARCOS").
- 479. The DEA ARCOS database reveals that Express Scripts purchased approximately 22.5 billion MMEs through its PBM mail order channel pharmacies. Specifically, during the 2006 to 2014 time period, Express Scripts mail order pharmacies bought over 22.9 billion MMEs spread over 1.1 billion opioid dosage units.
- 480. Not surprisingly, given their lengthy collaboration with regard to OxyContin, over 26% of Express Scripts pharmacies' MME purchases were for Purdue opioids.
- 481. 23.63% of Express Scripts pharmacies' opioid purchases were for Teva opioids; 14.38% were for Mallinckrodt opioids; 8.34% were for Endo opioids; and 4.59% were for Mylan opioids. Express Scripts pharmacies dispensed these opioid products by mail to patients nationwide, including in West Virginia and Plaintiffs' Communities.
- 482. From at least 2008 to the present (and ongoing), Express Scripts violated the CSA, West Virginia controlled substances laws (including the West Virginia Controlled Substance Act Act), and the United States and state (including West Virginia) pharmacy laws and regulations by dispensing controlled substances in violation of their corresponding responsibility under 21 C.F.R. § 1306.04(a) and outside the usual course of pharmacy practice under 21 C.F.R. § 1306.06.

- 483. Express Scripts violated the CSA, West Virginia controlled substances laws (including the West Virginia Controlled Substances Act), and the United States and state (including West Virginia) pharmacy laws and regulations each time their mail order pharmacies filled a controlled substance prescription without identifying and resolving those red flags because, *inter alia*:
 - (a) They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore, they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1); and
 - (b) They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. 1306.06, and therefore such dispensing and delivering of controlled substances was not authorized by the CSA, and thereby violated 21 U.S.C. § 841(a)
- 484. The opioid crisis alleged herein is a direct and foreseeable result of Express Scripts' actions and inactions. And, it was reasonably foreseeable that Plaintiffs and Plaintiffs' Communities would be damaged thereby.
- 485. Express Scripts failed to maintain effective controls against abuse and diversion or conduct adequate due diligence to ensure opioids were not diverted, resulting in the gross over-dispensing of opioids. Express Scripts thus directly contributed to today's opioid epidemic and corresponding harm to Plaintiffs and Plaintiffs' Communities.
- 486. The opioid nuisance alleged herein is a direct and foreseeable result of Express Scripts' actions and inactions. And it was foreseeable that Plaintiffs and their communities would be damaged thereby.

VIII. Facts Pertaining to the Formulary & UM Enterprise

487. As alleged above more fully *infra*, Express Scripts, its mail order pharmacies, and each of the prescription opioid manufacturers (including Allergan, Johnson & Johnson/Janssen, Endo, Insys, Mallinckrodt, Purdue, and Teva/Cephalon, referred to collectively as the "Opioid

Enterprise Manufacturers" for the purposes of this Section) formed an association in fact enterprise, the "Formulary & UM Enterprise."

- 488. The Formulary & UM Enterprise was characterized by a common purpose, relationships among members of the Formulary & UM Enterprise, and sufficient longevity to accomplish the common purpose thereof. Express Scripts conducted and participated in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity.
- 489. Each member of the Formulary & UM Enterprise knew that prescription opioids were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain. Each member of the Formulary & UM Enterprise was also aware that use of prescription opioids carried risks such as addiction, opioid use disorder, overdose, and death. Nevertheless, each member of the Formulary & UM Enterprise joined together into an association-in-fact enterprise for the common purpose of profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs.
- 490. That each member of the Formulary & UM Enterprise is a for-profit company and may legally pursue profits is not in dispute. However, each member of the Formulary & UM Enterprise sought to fulfill common purpose through a pattern of mail and wire fraud, and felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in controlled substances. Specifically, each member of the Formulary & UM Enterprise supported each other member in perpetrating a fraudulent scheme on the consumers who received prescriptions for prescription opioids, on the American public, and on Express Scripts' clients. Each member of the Formulary & UM Enterprise also supported each other member in feloniously possessing and dispensing controlled substances in Schedules II through IV in manners that were not authorized by the CSA.

- 491. Each member of the Formulary & UM Enterprise knew that prescription opioids were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain. Each member of the Formulary & UM Enterprise was also aware that use of prescription opioids carried risks such as addiction, opioid use disorder, overdose, and death. Therefore, each member of the Formulary & UM Enterprise knew that they needed to engage in a fraudulent scheme if they were going to increase the market for prescription opioids and increase their profits from prescribing, dispensing, and sales of prescription opioids.
- 492. For their part, the Opioid Enterprise Manufacturers' illegal marketing and false statements regarding prescription opioids have been well documented. They knew that prescriptions were dangerous and addictive and, nevertheless, marketed them as safe and non-addictive. These representations furthered the common purpose of the Formulary & UM Enterprise.
- 493. Express Scripts, for its part, made representations alleged, *supra*, that their businesses were committed to making decisions about their formulary and UM offerings that were driven by a commitment to the health and safety of their covered lives and were focused on delivering safe healthcare.
- 494. Express Scripts and opioid manufacturers also knew that Express Scripts' mail-order pharmacies were receiving prescriptions that were not for lawful orders of a practitioner. Express Scripts and opioid manufacturers knew that Express Scripts' mail-order pharmacies were filling illegitimate prescriptions.
- 495. By these strategies, and the activities alleged *supra* and *infra*, both Express Scripts and the Opioid Enterprise Manufacturers agreed to further the common purpose of the Formulary & UM Enterprise through a fraudulent scheme and felonious possession and dispensing of

controlled substances, and to grow the market for prescription opioids by increasing prescribing, dispensing, and sales of prescription opioids.

- 496. As an example, the Opioid Enterprise Manufacturers contracted and agreed with Express Scripts to coordinate unfettered formulary placement (with no or limited) UM measures regarding each opioid drug on Express Scripts' standard offerings, such that there would be as little impediment as possible to opioid prescribing and dispensing. From their agreements, each member of the Formulary & UM Enterprise stood to reap significant profits from ever-increasing prescribing, dispensing, and sale of prescription opioids: the Opioid Enterprise Manufacturers from sales of their drugs and Express Scripts from rebates and other fees. As part of these agreements, Express Scripts gave each of the Opioid Enterprise Manufacturers parity terms, ensuring that no Opioid Enterprise Manufacturer's opioid was disadvantaged against within each class of opioid analgesics, and provided the Opioid Enterprise Manufacturers with data about the lives that they managed, the prescriptions written by doctors on their plans, and assistance with pull through contracts to assist them in pulling through the formulary decisions which would continue to increase prescribing and sales.
- 497. These contracts, and further information described below, evidence an agreement between Express Scripts, its mail-order pharmacies, and the Opioid Enterprise Manufacturers. Express Scripts and the Opioid Enterprise Manufacturers understood that Express Scripts was going to operate on a fundamentally fraudulent basis. As alleged more fully *infra*, Express Scripts promised its clients it would take actions that would ensure that opioid prescribing and dispensing were safe and cost effective. Express Scripts also represented to legislative bodies and the public that its conduct was intended to maximize health, safety, and cost-effective healthcare for their covered lives. However, Express Scripts agreed with other PBMs and the Opioid Enterprise

Manufacturers that their conduct would have the opposite effect. Instead of prioritizing health, safety, and cost-effectiveness, the Formulary & UM Enterprise and its members intended to obtain money and property from the prescribing, dispensing, and sale of prescription opioids that they would not otherwise have received had they been honest and conducted their businesses along the lines of their public representations.

- 498. Importantly, some of the conduct alleged, above and below, may appear to be the behavior of competitors working against each other, or of opposing parties working to secure advantage at the expense of ether other. However, Express Scripts worked with other PBMs and the Opioid Enterprise Manufacturers in negotiations that were intended to maximize the amount of profit for Express Scripts and the Opioid Enterprise Manufacturers. As an example described earlier, discussion of formulary status and prior authorization were always a vehicle for discussion about the amount of rebates and administrative fees. As the Opioid Enterprise Manufacturers and Express Scripts knew and intended, the end result was always the same—agreements for favorable formulary status without UM so that prescribing, dispensing, and sales could continue to increase.
- 499. The similarity of conduct by Express Scripts compared to other PBMs, including similar contract terms, pull-through marketing, facilitating dissemination of the Opioid Enterprise Manufacturers' marketing messages, favorable formulary status, as little UM as possible, research on behalf of the Opioid Enterprise Manufacturers, and free-flowing dispensing of prescription opioids, further evidences the existence of the Formulary & UM Enterprise. Express Scripts knew of other PBMs' conduct and refrained from commenting on or revealing the behavior, and continued to engage in the same conduct so that all members of the Formulary & UM Enterprise could continue to profit from ever-increasing prescribing, dispensing, and sales.

- 500. That Express Scripts may have competed with other PBMs for clients, or negotiated sharply with the Opioid Enterprise Manufacturers for increasing rebates and administrative fees did not undercut the common purpose of the Formulary & UM Enterprise because it did not slow or decrease the overall prescribing, dispensing, and sale of prescription opioids in the market as a whole. Similarly, competition among the Opioid Enterprise Manufacturers for increasing market share of their drug against a competitor's drug did not undercut the common purpose of the Formulary & UM Enterprise. For example, Purdue's competition with Endo for market share of OxyContin over Opana did not slow or decrease the prescribing, dispensing, or sale of prescription opioids as a class of drugs. Furthermore, each member of the Formulary & UM Enterprise knew that there would be competition in the market, but each member also knew that their participation in the Formulary & UM Enterprise was necessary to continue growing the market and agreed to work together towards that goal.
- 501. As alleged more fully herein, the Formulary & UM Enterprise caused direct injury to each Plaintiff's money and property.

A. Formation of the Formulary & UM Enterprise

- 502. The Formulary & UM Enterprise was formed primarily in two ways, including: the forced dealing of the members with each other in the closed system of controlled substance manufacture, distribution, and dispensing, as well as the members work together in trade associations and industry working groups like the PCMA and other informal groups described below.
- 503. First, the formation of the Formulary & UM Enterprise occurred, in part, through the parties' dealings with each other required by the closed system imposed by the CSA. The pharmaceutical industry is extremely insular and part of a "closed system" open only to those who register to do so. Other than their CSA obligations as s mail order pharmacy, Express Scripts is

one of the few participants in controlled substance manufacturing, distribution and dispensing that are not required to register with the DEA. However, in its efforts to secure cost-effective access to controlled substances on behalf of their clients, Express Scripts were forced to work closely with the Opioid Enterprise Manufacturers.

- 504. Over at least the last two decades, the consolidation and acquisition of pharmacy benefit management companies into ever-larger entities has led to the formation of close personal business relationships between the few remaining PBMs and the Opioid Enterprise Manufacturers that were based on a shared interest in and the common purpose of ensuring the widespread dispensing of opioids.
- Manufacturers maintain interpersonal relationships with each other. As business entities, they have been negotiating with each other since the mid-1990s. And, as alleged above, the negotiations between the Opioid Enterprise Manufacturers and Express Scripts often took place at, and/or involved, high level executives at both companies, a multitude of emails and phone calls, including personal calls between executives to iron out details. The contractual dealings between the Opioid Enterprise Manufacturers and Express Scripts created relationships and provided context in which the common purpose of the Formulary & UM Enterprise could develop. Documents produced by the Opioid Enterprise Manufacturers and Express Scripts reveal that there have been decades of contract negotiations over rebate agreements, amendments, re-negotiations, payment discussions, and rebate invoicing. These contract negotiations were always geared towards maximizing the number of prescriptions written for Express Scripts' clients and ensure the most optimal formulary placement and least amount of UM under Express Scripts' standard offerings so that the prescribing, dispensing and sales could continue to grow.

- 506. The earliest indications of the existence of the Formulary & UM Enterprise can be found in Express Scripts' negotiations with Purdue, their work together on disseminating the Opioid Enterprise Manufacturers' marketing messages about prescription opioids, the presence of Purdue-paid speakers at Express Scripts' offices, and Express Scripts' research work supporting the Opioid Enterprise Manufacturers. Although the earliest indications of the Formulary & UM Enterprise's existence begin with Purdue and the predecessors of Express Scripts, the allegations above indicate that the Formulary & UM Enterprise grew to include all of the Opioid Enterprise Manufacturers and the consolidated PBMs now named as Defendants.
- 507. As alleged more fully herein, various documents indicate that the Formulary & UM Enterprise found its beginnings with Purdue-sponsored doctors speaking at PBM offices, in the late 1990s, all across the country, and rebate contract negotiations between the Opioid Enterprise Manufacturers and Express Scripts that began around the same time and have continued through the present.
- 508. The formation of the Formulary & UM Enterprise did not happen solely within the formation of the rebate contracts between the Opioid Enterprise Manufacturers and Express Scripts. The Formulary & UM Enterprise also continued to develop through regular non-contractual interactions, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme in: (1) interactions about the administration of the rebate contracts; (2) pull-through marketing and assistance therewith; and (3) joint participation in trade associations and informal coalitions.
- 509. Trade associations and informal coalitions and forums not only provide a basis for the formation of the Formulary & UM Enterprise, but also serve as central conduits for the conduct

of and participation in the Formulary & UM Enterprise.¹⁷⁸ The prime example of a trade association through which the Formulary & UM Enterprise developed and operated is the PBM's trade association, the Pharmaceutical Care Management Association ("PCMA").

- 510. PCMA describes itself as "lead[ing] the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs and increasing access." ¹⁷⁹
- 511. While PCMA boasts of being the national association representing America's pharmacy benefit managers, it actually has a much broader membership base and focus. As evident from the PCMA website, PCMA membership includes member PBMs and so-called "Affiliate" drug manufacturers and other entities, including numerous of the Opioid Enterprise Manufacturers as current or former members.
- 512. As repeatedly mentioned in the PCMA's annual conference materials, the drug manufacturers are the PBMs' most notable business partners.¹⁸⁰

¹⁷⁸ Pain Care Forum became 'echo chamber' for opiate distribution, epidemic in United States (Sep. 19, 2016) https://www.oxfordeagle.com/2016/09/19/pain-care-forum-became-echochamber-for-opiate-distribution-in-united-states/; see also, Geoff Mulvihill, Liz Essley Whyte et al., "Purdue Pharma, Pain Care Forum fought opioid limit 'domino effect' Groups wage battle against Washington state's efforts to curb opioid overuse," Times Union (Sep. https://www.timesunion.com/news/article/Purdue-Pharma-Pain-Care-Forumfought-opioid-9229680.php; Matthew Perrone, "Painkiller politics: Effort to curb prescribing under fire." (Dec. 2015) 18. https://apnews.com/article/765439c771b649a7b6940fda87595735; Scott Higham, Horwitz, Steven Rich and Meryl Kornfield, "Inside the Drive Industry's Plan to Defeat the DEA," TheWashington Post2019) (Sep. 13, https://www.washingtonpost.com/graphics/2019/investigations/drug-industry-plan-todefeat-dea/.

¹⁷⁹ About PCMA, https://www.pcmanet.org/about/ (last visited Oct. 11, 2023).

PCMA Annual Meeting 2016 Conference Program Book, https://www.pcmanet.org/events/past-events/2016-annual-meeting/ (last visited Dec. 5, 2023).

- The PCMA Annual Meeting is the industry's premier executive conference. The event is tailored specifically for sunior executives from PEMs and their affiliated business partners most notably drug manufacturers. We've
- 513. Express Scripts is a member of PCMA, and due to its leadership positions, has substantial control over PCMA.¹⁸¹ Indeed, PCMA is governed by PBM executives. The current board of PCMA includes Adam Kautzner, Pharm.D. (President of Express Scripts).
 - 514. An image illustrating the membership in the PCMA is as follows: 182



515. Active control over the PCMA Board of Directors is important to Express Scripts and clearly conditioned on current employment by the PBM. As an example, in 2022, former

¹⁸¹ PCMA Board of Directors, https://www.pcmanet.org/board-of-directors/ (last visited Oct. 11, 2023).

PCMA Annual Meeting 2016 Conference Program Book, https://www.pcmanet.org/events/past-events/2016-annual-meeting/ (last visited Dec. 5, 2023).

Express Scripts President Amy Bricker was the former Chair of the PCMA Board of Directors and the only Express Scripts employee on the Board. But, when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA Board. On February 3, 2023, PCMA issued a press release, naming Mr. Kautzner to the Board and as its Chair.

- 516. Each year during the relevant period, PCMA has regularly held industry conferences, including its Annual Meeting and Business Forum conferences.
- 517. Every year, high-level representatives and corporate officers from both Express Scripts and the Opioid Enterprise Manufacturers have attended these conferences to meet in person and engage in discussions, including those in furtherance of the Formulary & UM Enterprise.
- 518. In fact, many of the Opioid Enterprise Manufacturers have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PCMA conferences.
- 519. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, the Opioid Enterprise Manufacturers were permitted to host "private meeting rooms" that offer "excellent opportunities for interactions between PBM members, drug manufacturers, and other industry partners." ¹⁸³
- 520. Representatives from Express Scripts and the Opioid Enterprise Manufacturers have routinely met during the Annual Meetings and Business Forum conferences that PCMA holds (and the manufacturers sponsor) each year.

¹⁸³ PCMA, The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21, https://www.pcmanet.org/pcma-event/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Oct. 11, 2023).

- 521. In addition, all PCMA members, including Affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "an invitation-only LinkedIn Group and online networking community."¹⁸⁴
- 522. As PCMA members and Affiliates, Express Scripts and the Opioid Enterprise Manufacturers utilized both PCMA-Connect, as well as the meetings facilitated by PCMA (including at conferences), to exchange information and to reach agreements in furtherance of the Formulary & UM Enterprise.
- 523. Thus, PCMA served as a conduit of information between the Opioid Enterprise Manufacturers and Express Scripts on subjects like access to prescription opioids.
- 524. That the PCMA served as a conduit for the sharing of information, and the formation of collaborative partnerships is not reasonably disputable. PCMA hosts regular meetings during which PBMs and Opioid Enterprise Manufacturers, or "Pharma" as they are called by the PBMs, can discuss their coordinated and shared objectives/strategies. PCMA's website posts programs for its regular meetings that highlight the close and "[i]mperative" collaboration and partnership between the PBMs and the Opioid Enterprise Manufacturers. Some examples from the program agendas and/or booklets currently available on PCMA's website include:
 - (a) Hot Topics and Trends Impacting Today's PBM and Pharma Strategies;
 - (b) Meeting Patients Where They Are: Pharma and PBMs working to close gaps in care in the post pandemic era;
 - (c) Unlocking the Value of PBM and Small Manufacturer Relationships;
 - (d) Manufacturers and PBMs Working Together to Reward Innovation;
 - (e) PBM & Pharma Priorities, Opportunities and Challenges in 2022 and Beyond;

¹⁸⁴ PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Oct. 11, 2023).

- (f) PBM and Pharma Collaboration: Focusing on Patients and Value;
- (g) Collaboration Imperative—Identifying the Shared Interests of PBMs and Pharma;
- (h) Market Dynamics Driving the PBM and Pharma Relationship;
- (i) The Future of PBM-Pharma Relations and Negotiations;
- (j) How Health Care Companies are Using Data and Predictive Algorithms to Identify and Address the Opioid Crisis;
- (k) State of the PBM-Manufacturer Partnership;
- (l) Confronting the Crisis We Brought Upon Ourselves: America's Opioid Abuse Epidemic;
- (m) The PBM/Pharma Relationship in the Era of High Price Drugs; and
- (n) PBMs, Specialty Pharmacies and Pharma Program Alignment—Affordability, Adherence and Outcomes.
- 525. Notably, PCMA only publishes the agendas and booklets from its regular meetings going back to 2014. Plaintiffs are informed and believe that similar meetings would have been held, and topics discussed throughout the entirety of the relevant discovery period.
- 526. Given the foregoing, it is not surprising that Purdue viewed PCMA as a valuable source of information and coordination on subjects regarding prescription opioids and OxyContin. As examples, Purdue employees were notified about meetings at the PCMA conference in 2001 that discussed "oxy attacks as a predatory action on the part of the media or one of your competitors," and Burt Rosen (another Purdue employee) reached out to PCMA in 2014 to find the right person to connect with "on opioids." ¹⁸⁵
- 527. More broadly, produced documents show that PCMA (including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme) served as a clearinghouse for communication, discussion, consensus building and speaking on

¹⁸⁵ PDD8801103934 (3/16/01); PPLPC018001107944 (10/2/14).

behalf of Express Scripts and the Opioid Enterprise Manufacturers who were Affiliate members. Documents confirm that PCMA was a conduit through which discussions occurred and consensus could be reached (including discussion between Express Scripts outside of official PCMA correspondence) and that specific discussions and work took place around efforts to curb opioid abuse (which would have worked against the common purpose of the Formulary & UM Enterprise).

528. PCMA was not the only way in which Express Scripts and the Opioid Enterprise Manufacturers collaborated. Additional documents show that the members of the Formulary & UM Enterprise knew how to, and did form, ongoing informal coalitions that for years met regularly to work on issues of common concern and advance their common interests. These documents show that a Controlled Substances Stakeholder's Coalition was formed in October 2013 in order to "further collaborate on interprofessional efforts to combat the United States opioid epidemic." At the time of the Coalition meeting in December 2016, these meetings had been ongoing for at least three years with each organization providing "updates for increasing awareness and decreasing misuse and diversion." ¹⁸⁶

529. Express Scripts claimed that it was making recommendations to physicians that had substantially decreased opioid prescriptions and taking actions to increase depository sites for drug disposal. As alleged more fully herein, however, documents confirm that Express Scripts was at the same time, in order to protect its shares of rebates and other fees, actively working with the Opioid Enterprise Manufacturers in the Formulary & UM Enterprise to avoid taking actions that would have reduced prescribing, thus ignoring their obligations to reduce unsafe and inappropriate prescribing.

 $^{^{186}}$ *Id*.

- 530. Finally, documents will show that groups like PCMA supported the formation of the Formulary & UM Enterprise and agreements within it:
 - (a) "The Coalition discusses the terms 'drug abuse' and 'addiction' versus 'substance use disorder,' . . . and agreed;"
 - (b) "Members then discussed the purpose of the slide deck . . . and agreed;"
 - (c) "Additionally, the Coalition discussed various communication strategies Members agreed;" and
 - (d) "Members unanimously agreed that further meetings were necessary to ensure that continued progress would be made." ¹⁸⁷
- 531. Members of the Formulary & UM Enterprise also participated in similar stakeholder meetings directly and/or through PCMA regarding topics like red flags and warning signs related to prescribing and dispensing controlled substances. The express purpose of these stakeholder meetings was to foster open channels of communication, foster understandings, and to discuss collaborative actions. Notably, membership in some stakeholders' meetings and working groups included some of the Opioid Enterprise Manufacturers' front groups and trade association (PhRMA), opioid distributors, the National Association of Chain Drug Stores, and other PBMs and pharmacies.
- 532. The foregoing facts, and as alleged in more detail herein, demonstrate that the Formulary & UM Enterprise arose from personal business relationships developed between the enterprise members in various ways over the course of at least the last two decades.

 $^{^{187}}$ *Id*.

PPLPC019001069664 (11/14/2014); PPLPC019001069666 (11/14/2014); PPLPC019001100901 (2/26/2015); PPLPC019001100905 (2/26/2015); PPLPC019001100919 (2/26/2015); PPLPC019001100921 (2/26/2015).

B. The Common Purpose and Fraudulent Scheme of the Formulary & UM Enterprise

- 533. The personal business relationships that formed the Formulary & UM Enterprise also allowed for the formation of a common purpose between the Opioid Enterprise Manufacturers and Express Scripts in the Formulary & UM Enterprise. Specifically, the Formulary & UM Enterprise was formed for the common purpose of illegally and fraudulently profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs. As alleged more fully herein, the fraudulent scheme that furthered the common purpose of the Formulary & UM Enterprise relied on fraudulent representations from Express Scripts to each one of its clients and to the public that it would structure formulary offerings and perform cDUR benefit services in the interests of its clients and patients to ensure that opioids were prescribed and dispensed only for safe and legitimate reasons. Instead of providing standard formulary and UM offerings that were in their clients' best interests or for safe and legitimate reasons, Express Scripts made decisions that gave the Opioid Enterprise Manufacturers and their prescription opioids unfettered and preferred formulary access, without utilization management, and did not disadvantage any opioid compared with another in the same class or formulary tier, agreed to parity treatment for opioids within the same class and/or formulary, supported the Opioid Enterprise Manufacturers' pull-though marketing, pocketed enormous rebates and other fees, and (through its mail order pharmacies) dispensed prescription opioids without conducting the necessary due diligence.
- 534. Each member of the Formulary & UM Enterprise played a part and furthered the common purpose of the Formulary & UM Enterprise.
- 535. For their part, the Opioid Enterprise Manufacturers have been engaged in fraudulent conduct related to the marketing of prescription opioids beginning in the mid-1990s.

As alleged by multiple entities and proven through extensive briefing, the Opioid Enterprise Manufacturers engaged in a fraudulent scheme, including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, to grow the market for prescription opioids through the use of branded and unbranded marketing materials, key opinion leaders ("KOLs") to give speaker presentations and publish about prescription opioids, and front groups which would contribute to and publish books, articles, documents, etc., all of which misrepresented the benefits and risks of prescription opioid use.

- 536. The Opioid Enterprise Manufacturers commonly made the same misrepresentations through common KOLs and Front Groups. For example, each of the Opioid Enterprise Manufacturers made repeated misrepresentations about the risks and benefits of prescription opioids, including:
 - (a) The risk of addiction from chronic opioid therapy is low;
 - (b) To the extent there is a risk of addiction, it can be easily identified and managed;
 - (c) Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
 - (d) Opioid withdrawal can be avoided by tapering;
 - (e) Opioid doses can be increased without limit;
 - (f) Long-term opioid use improves functioning;
 - (g) Alternative forms of pain relief pose greater risks than opioids;
 - (h) OxyContin provides twelve hours of pain relief; and
 - (i) New formulations of certain opioids, labeled abuse deterrent, successfully deter abuse.
- 537. Each of the Opioid Enterprise Manufacturers made nearly identical representations about their branded drugs and/or unbranded prescription opioids as a class of drugs during the relevant time period.

- 538. Each of the Opioid Enterprise Manufacturers used similar Front Groups to promote prescription opioid use. As examples, multiple of the Opioid Enterprise Manufacturers used Front Groups including, as examples, the following: the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, Federation of State Medical Boards, the Alliance for Patient Access, the United States Pain Foundation, the American Geriatric Society, and the National Initiative on Pain Control.
- 539. The Opioid Enterprise Manufacturers took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that the Opioid Enterprise Manufacturers were consistently in control of their content and that it stayed on message in favor of more opioid prescribing. The Opioid Enterprise Manufacturers exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and, through the Front Groups, with each other to deceptively promote the use of prescription opioids.
- 540. Each of the Opioid Enterprise Manufacturers used similar Key Opinion Leaders and the strategy of paying opinion leaders and speakers who favored aggressive treatment of pain with prescription opioids. Pro-opioid doctors have been at the hub of the Opioid Enterprise Manufacturers' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that opioids were safe and efficacious. As examples, multiple Opioid Enterprise Manufacturers used similar Key Opinion Leaders including, but not limited to: Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman.
- 541. Each of these Key Opinion Leaders and numerous other, lower profile doctors, were paid to speak on behalf of prescription opioids as an unbranded class of drugs. They were used extensively to present the appearance that unbiased and reliable medical research supported

the broad use of prescription opioids. These pro-opioid doctors also began to write, consult on, edit, and lend their names to books and articles, they gave speeches, they served on committees, etc., all the while encouraging the use of prescription opioids.

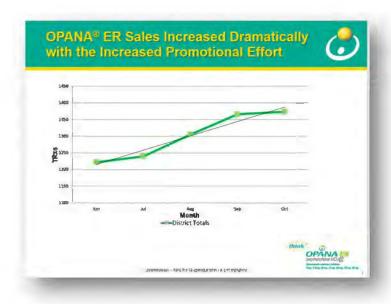
- 542. The Opioid Enterprise Manufacturers' marketing conduct did not end with the KOLs and Front Groups—they were merely one of the vehicles for the dissemination of the misrepresentations. The Opioid Enterprise Manufacturers also used branded and unbranded advertising and marketing; funded, edited and distributed pro-opioid publications; speakers bureaus and continuing education programs. Examples of speakers' bureaus and continuing medical education events occurring at Express Scripts' facilities are found throughout document productions from the Opioid Enterprise Manufacturers. Furthermore, as alleged above, Express Scripts often facilitated and/or disseminated the Opioid Enterprise Manufacturers' marketing messages directly to doctors who prescribed for patients covered by Express Scripts' clients.
- 543. One of the primary means by which the Opioid Enterprise Manufacturers disseminated their messaging about prescription opioids was through drug detailing: the practice of sending out pharmaceutical company representatives to provide details about specific branded products in order to persuade prescribers to begin writing (or write more) prescriptions for a specific product.

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Purdue-produced documents 7003172769 (Merck Medco Speaker Program Dallas approved by Purdue 4/27/01); 7003178877 (United Healthcare-St Louis speaker program approved by Purdue 3/11/01); 7003178881 (related, 5/22/01); 7003178889 (United Healthcare of Rhode Island speaker program approved by Purdue on 3/30/01); 7006607303 (Merck-Medco speaker program to occur in Columbus, OH approved by Purdue on 9/10/99); 7006622039 (Merck-Medco speaker approval in New York approved by Purdue on 2/22/11); 7007850486 (Merck-Medco speaker approval in Mechanicsburg, PA approved by Purdue on 4/6/99).

- 544. The Opioid Enterprise Manufacturers adopted detailing as a key component of their prescription opioids strategy early on to capitalize on the fraudulent unbranded marketing—developing carefully crafted marketing messages and tactics to deliver messages to prescribers through close relationships with sales representatives.
- 545. Drug detailing is data driven, requiring identification of the prescribers who are writing high or low volumes of prescriptions, targeting places where additional messaging might be affecting and to test the effectiveness of messaging. In accordance with common industry practice, the Opioid Enterprise Manufacturers purchased and closely analyzed prescription sales data from companies like IMS Health (now IQVIA) and Express Scripts which allowed it to track—precisely—the rates of initial and renewal prescribing by individual prescribers.
- 546. The nexus between data and detailing helped drive the formation of the common purpose of the Formulary & UM Enterprise. In return for data and unfettered formulary placement from Express Scripts, the Opioid Enterprise Manufacturers were willing to pay higher rebates and other fees to Express Scripts.
- 547. Once that occurred, Express Scripts once again supported the Opioid Enterprise Manufacturers' fraudulent marketing regarding prescription opioids. After the Opioid Enterprise Manufacturers obtained Express Scripts' data and favorable formulary placement, the Opioid Enterprise Manufacturers' sales personnel immediately began to analyze their managed care or PBM data in order to "pull through" the formulary placement in order to drive increased sales. Documents produced from the Opioid Enterprise Manufacturers and Express Scripts are replete with examples of pull-through initiatives touting the beneficial formulary placement of Opioid Enterprise Manufacturers' drugs to drive increased sales and use of Express Scripts' data to maximize the pull through effort.

548. These documents make clear that the formulary placement was viewed as a "win" and an opportunity to make the rebate agreements profitable by pulling through sales. Sophisticated presentations outlining the exact steps a sales representative should take were often included in the sales training materials. The impact of these agreements and the ability to pull-through increased sales using the PBM data was dramatic:

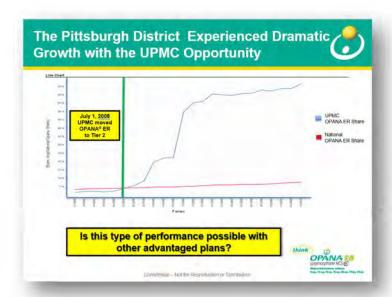


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549. Using the "Best Practices Identified" of: 1. Identifying the local UHC MC Opportunity; 2. Targeting the Right UHC Customer; 3. Hyper Targeting; 4. Delivering the Right Message; and 5. Consistent Cross-Functional Communication¹⁹¹ – the Pittsburgh District experienced dramatic growth in sales, as described by Endo:

¹⁹⁰ ENDO-CHI LIT-00046379, slide 7.

¹⁹¹ *Id.* at slide 10.



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- 550. Formulary wins were a boon for each member of the Formulary & UM Enterprise. Each prescription opioid that enjoyed a favorable formulary placement, or continued to enjoy prescribing and dispensing without UM, ensured that all prescription opioids would continue to enjoy unrestricted sales due to the privity clauses that Express Scripts agreed to with each Opioid Enterprise Manufacturers. And, as indicated by the graph cited above, these wins increased sale. And, by increasing sales, the wins increased profits for the Opioid Enterprise Manufacturers whose drugs were sold and for the PBM who received rebates and administrative fees tied to sales. From that perspective, the graph above is literally evidence of the Formulary & UM Enterprise and its common purpose.
- 551. As alleged in more detail herein, Express Scripts took on obligations to perform and made representations that it would conduct point-of-sale review, and take actions to ensure that only safe and legitimate prescriptions were being filled when they had no intention of doing so. Had Express Scripts taken the actions they had promised their clients, it would have

¹⁹² *Id.* at slide 9.

dramatically reduced medically inappropriate prescribing, sales and dispensing of prescription opioids. As alleged more fully herein, Express Scripts' failure to do so had a significant role in allowing opioids to flood into communities across America, including into Plaintiffs' Communities.

- 552. Express Scripts also paid lip service to their commitment to taking action about prescription opioids. For example, Express Scripts represented in 2013 that it was "leading the fight against prescription drug fraud, waste and abuse." ¹⁹³
- 553. But Express Scripts' claims that it was addressing fraud, waste, and abuse were only empty promises. For example, one former Fraud, Waste and Abuse investigator for Express Scripts from 2013 to 2019, Confidential Informant No. 1 (CI-1), explained that even when they identified blatant instances of pill seekers and pill mill doctors, nothing happened. "No one really cared," he said. "No one really followed up on anything. The members were just like a number. We'd totally forget this was a human being because it was just a case number. We'd just look at it, type it up and it was gone. They never got the help they needed. I never heard this person is in rehab."
- 554. Moreover, as far as CI-1 knew, none of his findings were ever shared with law enforcement, even if it involved well documented pill mill doctors or pill seekers.
- 555. CI-1 explained that, when he was hired, he thought he would be investigating "serious major fraud, all of these people writing all of these false prescriptions," he said. "I just thought it was more investigation stuff." They would re-run patients and doctors' names every five months, he said. "We'd see the same people over and over," he said. "Just because we identified the behavior didn't mean it stopped. We'd just call the doctors and they didn't even care. They just

¹⁹³ PPLPC019000862211 (11/18/13).

felt this patient was in pain, but we're not going to do anything about it. It wouldn't be rare to have [the bad doctors] written up twice in a year. . . . I'd say 90 percent of the reports never got read in my opinion. . . . Let's say I spent months, sometimes weeks on a report—it's being written for the manager. It really doesn't go anywhere else."

- 556. Similarly, PCMA and some of its PBM members participated in coalitions or external activities indicating that they were "increasing awareness and decreasing misuse." However, the internal documents produced by Express Scripts show a different story and uncover the fraudulent nature of the PBM Enterprises. Express Scripts did not make decisions based on the terms of the contracts with their clients or in order to fight drug abuse and/or diversion. Rather, Express Scripts made decisions in order to protect their rebates and generate profit, despite concerns about prescription opioids and the companies that sold them.
- 557. Express Scripts hid these facts from their clients. In a telling exchange in 2002, when Highmark Blue Cross Blue Shield decided it would put a 300mg daily limit on a drug, Medco pushed back because this meant that Medco would lose Purdue rebates if there was a limit below 320mg per day. Here, as alleged, was evidence that an action could have been taken to drastically limit inappropriate prescribing, sales and dispensing, but it was ignored in favor of the action that advanced the common purpose of the Formulary & UM Enterprise. Instead of taking action to limit medically unnecessary and inappropriate prescribing, sales and dispensing, an August 18, 2002, email from Purdue National Account Director Bernadette Katsur reveals that a Medco Vice President convinced its client—Highmark—to drop its daily dosage limit.

¹⁹⁴ CAH_MDL2804_01524873 (12/15/16) (also indicating that Express Scripts had "[d]eveloped a matrix for making recommendations).

- 558. Documents created in the mid-2010s confirm that Express Scripts regularly delayed taking actions that could have dramatically reduced medically inappropriate prescribing, sales and dispensing despite promises from Express Scripts to do the same.
- 559. Here, again, Express Scripts did not take action that it could have taken to block inappropriate prescription opioid dispensing.
- 560. Express Scripts went through issues with OxyContin prescribing. In a March 2017 email, there were several employees from Express Scripts who derided the decision by the Express Scripts Value Added Committee to overrule the prior authorization limit on OxyContin, stating that the decision did not sit well with them at all. As Express Scripts employees noted, this decision made no clinical sense. Without question, the prior authorization limit would have dramatically reduced medically inappropriate prescribing, sales, and dispensing which would have impacted "rebate gain."
- 561. But Express Scripts' involvement did not end there. As alleged more fully herein, Express Scripts owns and operates mail order pharmacies. As alleged above, each of Express Scripts' mail order pharmacies dispensed massive amounts of branded and generic opioids without performing the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be resolved through due diligence. As such, the mail order pharmacies provided another mechanism for the goal of the Formulary & UM Enterprise—*i.e.*, the unrestricted increase in prescribing and dispensing of prescription opioids for the profit of the Opioid Enterprise Manufacturers and Express Scripts.
- 562. By dispensing branded and generic prescription opioids without performing the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be resolved through due diligence, Express Scripts' mail-order pharmacies furthered the common purpose of

the Formulary & UM Enterprise. They continued to facilitate the increased dispensing and sale of prescriptions opioids. However, this also violated the law governing dispensing controlled substances in Schedules II through IV in ways that are punishable as felonies.

563. As alleged more fully herein, the Formulary & UM Enterprise maintained a common purpose from the late 1990s through to the present day, creating sufficient longevity in their personal business relationships for them to pursue the common purpose of the Formulary & UM Enterprise.

C. Conduct and Participation of the Formulary & UM Enterprise Through a Pattern of Racketeering Activity

- 564. The common purpose of the Formulary & UM Enterprise alleged more fully herein was perpetrated through a fraudulent scheme fulfilled by multiple acts of mail fraud and wire fraud, and by felonious possession and dispensing of controlled substances. Express Scripts predicate acts of racketeering constituting a pattern of racketing activity.
- 565. The pattern of racketeering activity used by Express Scripts and its mail order pharmacies likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme through which the common purpose was achieved.
- 566. Use of the mail and wire facilities began with the formation of the Formulary & UM Enterprise. Negotiations and communications about the contracts between Express Scripts and the Opioid Enterprise Manufacturers occurred through interstate mail and wire facilities and involved meetings, communications, and negotiations about contracts between Express Scripts and the Opioid Enterprise Manufacturers, the Opioid Enterprise Manufacturers' marketing and Express Scripts assistance therewith, and pull-through marketing which required the transmission of large volumes of data.

- 567. As alleged more fully herein, the Opioid Enterprise Manufacturers and Express Scripts regularly and continuously communicated through the use of the U.S. Mail and interstate wire facilities in furtherance of the common purpose of the Formulary & UM Enterprise and their fraudulent scheme, including discussions of formulary placement, prior authorization limits, step edits, preferred formulary status and their impact on opioid prescribing and dispensing and, relatedly, rebates and other fees. Importantly, rarely mentioned during these discussions was the impact of the burgeoning opioid epidemic. These discussions were clearly intended to further the common purpose of the Formulary & UM Enterprise, happened over at least the last two decades (beginning with Purdue's work with predecessors of Express Scripts and continuing to involve more Opioid Enterprise Manufacturers over time), and reveal the ongoing personal business relationships that developed between the members of the Formulary & UM Enterprise.
- 568. Similarly, Express Scripts engaged in significant pull-through marketing assistance with each Opioid Enterprise Manufacturer. As revealed by documents cited herein, each of Express Scripts, through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, agreed to provide the Opioid Enterprise Manufacturers with preferred formulary placement and prescribing data. This ensured that the unfettered formulary access (granted despite Express Scripts' contrary representations to the public and their clients), would facilitate unrestricted opioid prescribing and dispensing. Documents confirm these facts and evidence that unrestricted formulary access was a boon for each Opioid Enterprise Manufacturers marketing efforts and that "pull through" efforts were undertaken after each formulary announcement "win" in order to drive the Opioid Enterprise Manufacturers' profitability. Express Scripts was not only aware of this pull through marketing, but they also actively joined in efforts

with the Opioid Enterprise Manufacturers by creating reports about the "value proposition" of unrestricted use of prescription opioids as alleged more fully herein.

- 569. Finally, Express Scripts and the Opioid Enterprise Manufacturers regularly (and through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme) participated in trade industry associations and informal coalitions that provided recurring non-contractual opportunities and forums in which to continue developing personal business relations and in which they form a common purpose of growing the unfettered use of opioid drugs.
- 570. Express Scripts engaged in essentially uniform conduct with the Opioid Enterprise Manufacturers whereby Express Scripts granted the Opioid Enterprise Manufacturers' drugs unfettered formulary access (including preferred formulary placement coupled with refraining from UM) despite their public promises and contractual obligations to make formulary and UM decisions in their clients' best interests, and facilitated their pull through marketing and/or directly facilitated the dissemination of their marketing messages. Express Scripts also provided the Opioid Enterprise Manufacturers with PBM data so that they could pull through the formulary "wins" and drive increased prescribing. At the back end of the fraudulent scheme, Express Scripts profited from its fraud by receiving rebates and other fees while the Opioid Enterprise Manufacturers enjoyed increased sales through pull through marketing and unfettered formulary access.
- 571. The fraudulent scheme was advanced through mailings and interstate wire transmissions that constitute racketeering activity. Collectively, these violations constitute a pattern of racketeering activity, through which Express Scripts and its mail order pharmacies and the Opioid Enterprise Manufacturers defrauded and intended to defraud consumers in West Virginia and Plaintiffs' Communities, the State, and other intended victims.

- 572. Express Scripts and its mail order pharmacies devised and knowingly carried out an illegal and fraudulent scheme using materially false or fraudulent pretenses, representations, promises, or omissions regarding their conduct. Specifically, as alleged more fully herein, Express Scripts promised to perform pharmacy benefit management services, including cDURs, formulary decisions, and UM decisions in their clients' best interests and in ways that would ensure safe and effective prescribing. As alleged herein, Express Scripts further represented to its clients and the public that it was committed to preventing and addressing misuse, abuse, and diversion of prescription opioids. These promises were made in person, in publications, and through the mail and the wires.
- 573. Express Scripts and its mail order pharmacies did not intend to comply with its contractual obligations, the promises to its clients, or its public representations. Express Scripts and its mail order pharmacies intended to continue to make decisions and take actions that benefitted the members of the Formulary & UM Enterprise and its common purpose by: failing to perform cDURs, granting unfettered formulary access, and blocking implementation of any UM measures. All told, Express Scripts and its mail order pharmacies intended to take actions that directly contradicted their promises, contractual obligations and public promises because they supported increased prescribing, sale, and dispensing of prescription opioids with as little inhibition or impediments as possible.
- 574. Express Scripts and its mail order pharmacies intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities intentionally and knowingly with the specific intent to advance and for the purpose of executing the illegal and fraudulent scheme.

- 575. By engaging in their intended conduct, as alleged more fully herein, Express Scripts and its mail order pharmacies engaged in fraudulent and unlawful conduct constituting a pattern of racketeering activity.
- 576. Express Scripts and its mail order pharmacies used the U.S. Mail and interstate wire facilities to perpetrate the fraudulent scheme of the Formulary & UM Enterprise with thousands of communications, publications, representations, statements, electronic transmissions, and payments including, but not limited to:
 - (a) Contracts negotiated and circulated between members of the Formulary & UM Enterprise;
 - (b) Contracts negotiated and circulated between Express Scripts and their clients;
 - (c) Public representations by the Opioid Enterprise Manufacturers and Express Scripts about their commitment to addressing misuse, abuse, and diversion of prescription opioids;
 - (d) Marketing materials about prescription opioids transmitted between the Opioid Enterprise Manufacturers and Express Scripts that were later disseminated by Express Scripts;
 - (e) Communications between Express Scripts and their clients about its commitment to following the terms of their respective contracts;
 - (f) Communications between the Opioid Enterprise Manufacturers and Express Scripts regarding formulary changes;
 - (g) Communications between the Opioid Enterprise Manufacturers and Express Scripts regarding and including PBM prescribing data;
 - (h) Transmission of rebate payments; and
 - (i) Transmission of payments from the clients of Express Scripts.
- 577. To achieve the common purpose of the Formulary & UM Enterprise, Express Scripts and its mail order pharmacies and the Opioid Enterprise Manufacturers hid from their clients, patients, regulators and Plaintiffs: (a) the fraudulent nature of the scheme; (b) the fraudulent

nature of their representations; (c) their intention to ignore their contractual cDUR obligations; (d) intent to make formulary and UM decisions that failed to limit the medically unnecessary and inappropriate prescribing, sales, or dispensing of prescription opioids or address misuse, abuse, and diversion; and (e) the true nature of the association between each member of the Formulary & UM Enterprise.

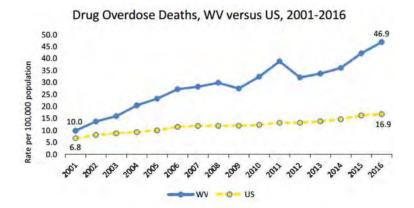
- 578. Each member of the Formulary & UM Enterprise, including Express Scripts and its mail order pharmacies, agreed with the overall objective of the Formulary & UM Enterprise's fraudulent schemes and participated by taking action that furthered the common purpose of the Formulary & UM Enterprise, including in the common course of conduct to commit acts of fraud and indecency.
- 579. The pattern of racketeering activity involving the felonious possession and dispensing of controlled substances in Schedules II through IV likely involved thousands, if not millions, if improperly dispensed prescriptions for branded and generic prescription opioids in violation of the CSA and Express Scripts' registrations as mail-order pharmacies. Express Scripts knowingly and intentionally possessed and dispensed branded and generic prescription opioids for reasons that were not authorized by the CSA.
- 580. The predicate acts of the Formulary & UM Enterprise all had the purpose of furthering the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue for Express Scripts and its mail order pharmacies. The predicate acts were committed, and/or caused to be committed, by Express Scripts and its mail order pharmacies through their participation in the Formulary & UM Enterprise and in furtherance of their fraudulent schemes, felonious possession and dispensing of controlled substances, and common purpose thereof.

IX. Express Scripts Contributed to the Public Health Crisis in West Virginia and in each Plaintiff's Community.

- 581. Fueled in part by Express Scripts' conduct as described above, the United States and West Virginia are in the midst of one of the deadliest and worst public health crisis in its history—the opioid epidemic.
- 582. By conspiring with and aiding and abetting the opioid manufacturers, facilitating the overprescribing and overuse of opioids, failing to address evidence of the misuse, abuse, and addiction to opioids, and failing to prevent diversion in their mail order dispensing and in their pharmacy networks, Express Scripts contributed to the oversupply of prescription opioids in West Virginia and in each Plaintiff's Community, and the resulting damages and public nuisance.
- 583. According to the CDC, the nation is experiencing an opioid-induced "public health epidemic." The CDC reports that over 1,000,000 people died from an overdose involving opioids from 1999 until present. Based on the latest data, approximately 3 million Americans met criteria for prescription opioid abuse and dependence in 2022. Since 1999, the amount of prescription opioids dispensed in the United States and the number of overdose deaths involving opioids have both quadrupled.
- 584. In addition to the toll on families and loved ones, opioid use imposes significant economy-wide costs. The U.S. Congress Joint Economic Committee estimates the opioid epidemic cost \$1.04 trillion in 2018, \$985 billion in 2019 and nearly \$1.5 trillion in 2020 alone, up 37% from 2017 when the CDC last measured the cost. The rise in fatal opioid overdoses in 2022 suggests the total cost is likely to continue to increase.
- 585. West Virginia is ground-zero of the opioid epidemic that Express Scripts caused, contributed, and maintained and is experiencing a drug overdose epidemic that is causing

devastating socio and economic consequences throughout the State, including in each Plaintiff's respective Community.

- 586. Between 2006 and 2014, the State of West Virginia was flooded with approximately 1.1 billion hydrocodone and oxycodone pills. The massive over-shipment amounts to 611 pain pills for every man, woman and child in the state of West Virginia.
- 587. As the volume of prescription opioids flooding into West Virginia increased, so, too, did the death toll.

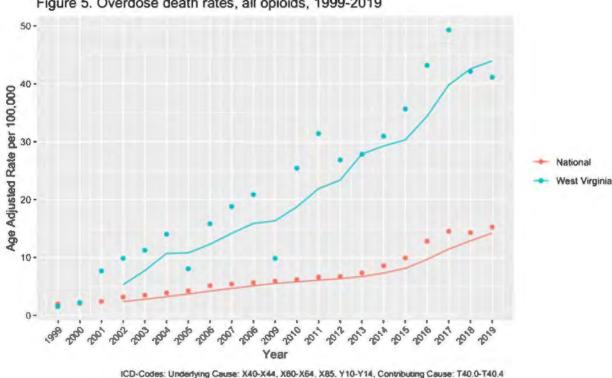


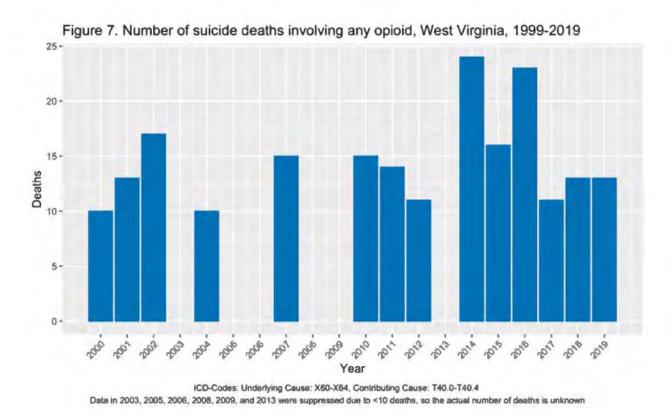
Source: West Virginia Board of Pharmacy, Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County, October 2017

- 588. West Virginia has had the highest opioid overdose death rate in the nation for the last ten out of ten years. The State also has one of the highest prescription rates of opioids in the United States. West Virginia ranks in the top 10 for the highest rate of prescriptions given out for high-dose opioids and extended-release opioids both of which are targets for abusers.
- 589. For over a decade, West Virginia has been at the top, if not led the nation, in prescription drug overdose deaths.

¹⁹⁵ See ARCOS Data produced in MDL 2804. Unless otherwise stated, distribution statistics throughout the Complaint are from this ARCOS Data.

- 590. West Virginia is the state with the highest age-adjusted death rate from opioid use over this time period; in terms of absolute deaths, from 1999 to 2019 there have been a total of 10,054 drug overdose deaths in West Virginia.
- 591. More specifically, deaths in West Virginia that listed opioids as a cause of death have also increased, from 1.55 per 100,000 in 1999 to 37.27 per 100,000 in 2019. In terms of per capita rates, compared to the national average, West Virginia has had the highest rate of opioid overdose in the country from 1999 to 2019.





- 592. Opioid prescribing rates in West Virginia are among the highest in the country. For example, in 2012, West Virginia providers wrote 137.6 opioid pain reliever prescriptions per 100 people, the third highest prescribing rate in the country and far above the U.S. rate (82.5/100).
- 593. The increased volume of opioid prescribing and the volume of opioids in West Virginia correlates directly to skyrocketing addiction, abuse, overdose, and death in West Virginia; black markets for diverted prescription opioids; and a concomitant rise in heroin, fentanyl, and methamphetamine abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.
- 594. Data from the West Virginia Center of Health Statistics corroborates that the overdose crisis in West Virginia began with prescription opioid overdose deaths and later transitioned to synthetic opioid overdose deaths. ¹⁹⁶ The available data sources on opioid-related

¹⁹⁶ West Virginia Health Statistics Center. Vital Statistics System Drug Overdose Database.

death in West Virginia demonstrate that there has been a major burden and epidemic of opioidrelated deaths in West Virginia for over twenty years, and that the epidemic was caused by an oversupply of prescription opioids.

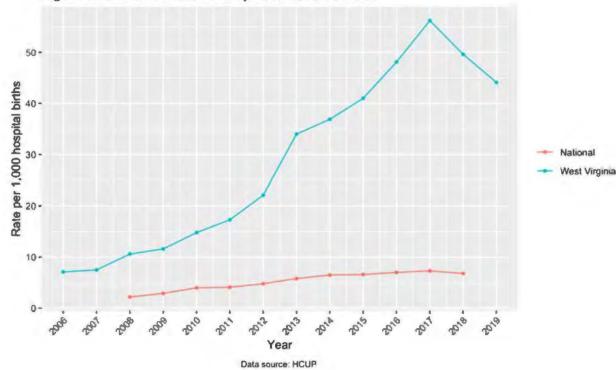
- 595. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription pain medication are 40 times more likely to be addicted to heroin.
- 596. The opioid epidemic coincided with increases in blood-borne infectious diseases tied to intravenous drug use which are now more prevalent and common throughout West Virginia. West Virginia's severe opioid epidemic has led to larger increases in its incidence rate of hepatitis B and C over the period 2010-2014 compared with changes in the national rate. The state's incidence rate of hepatitis B was 10.10 cases per 100,00 population in 2014, which is the highest rate in the nation and more than 10 times the national rate; its incidence rate of hepatitis C is the second highest in the nation and about five times the national rate. ¹⁹⁷
- 597. Infants and children are particularly vulnerable to the opioid epidemic in West Virginia. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. When untreated, NAS can be life-threatening.

¹⁹⁷ May 2017 Mayor's Office of Drug Control Policy, Huntington, West Virginia.

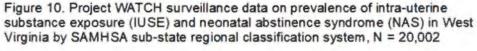
598. There has also been a startling increase in infants born with Neonatal Abstinence Syndrome (NAS) in West Virginia:

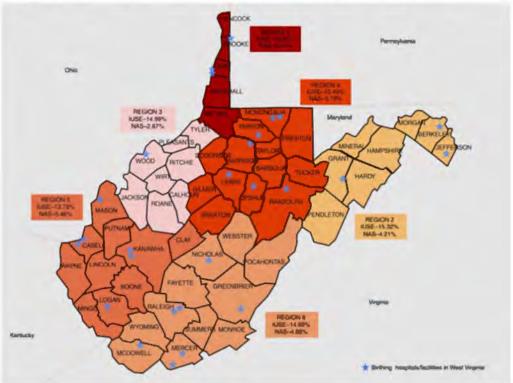
Number of NAS Newborn Hospitalization in West Virginia													
2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019		
216	240	293	326	436	668	737	N/A	930	1017	891	761		

Figure 9. Neonatal abstinence syndrome, 2006-2019



599. Indeed, the rate of NAS in West Virginia more than quintupled from 2008 to 2017, from 10.64 per 1,000 births in 2008 to 56.17 per 1,000 births in 2017.





- 600. In West Virginia, the rate of opioid-related inpatient hospital treatments more than doubled in less than 10 years, from 218 per 100,000 in the first quarter of 2009 to 465 per 100,000 in the second guarter of 2019.
- 601. Medical and expert evidence indicates that in 2019, the prevalence of Opioid Use Disorder ("OUD") was approximately 4% in West Virginia.
- 602. Given the approximate 72,032 adults in West Virginia experiencing mild to severe OUD, there have been serious consequences of opioid use to children in West Virginia, with an estimated 42,500 children in West Virginia being exposed to parental opioid use during adolescent development. An estimated 4,000 children in West Virginia have had a parent die from overdose or another opioid-related cause. *Id.* at 14 (citing Brundage SC, Fifield A, Partridge L. The ripple

effect: national and state estimates of the U.S. opioid epidemic's impact on children. United Hosp Fund. Published online 2019).

- 603. As described above, the opioid epidemic has created a strain on the foster care system as it is now "stretched dangerously thin." Additionally, approximately 40% of foster care system placements in West Virginia are due to parental drug use, a substantial portion of which would be expected to be opioid use given the high burden of addiction in West Virginia. Overall, approximately 8.6 children per 1,000 in West Virginia are separated from families due to concerns about child welfare, which is higher than any other state in the United States. *Id.* (citing Kinder R. Kids in care: where are all the children in foster care? Charleston Gazette-Mail. 2019).
- 604. Within West Virginia, Plaintiffs' Communities have been particularly ravaged by the opioid epidemic caused by Express Scripts' wrongful actions. Plaintiffs' Communities have each suffered from opioid related addiction, abuse, overdose, and death which has had severe and far-reaching public health, social services, and criminal justice consequences, health, social services, and criminal justice consequences which have created a significant and unreasonable interference with the public health, the public safety, the public peace, the public comfort and/or the public convenience in Plaintiffs' Communities.
- 605. As a result of Express Scripts' conduct and actions, Plaintiffs' Communities were flooded with prescription opioids. According to ARCOS data, between 2006 and 2019, Plaintiffs were inundated and flooded with oxycodone, hydrocodone, and other prescription opioids:

County	Total Rx Pain Pills (Hydrocodone + Oxycodone), 2006-2019	Rx Pain Pills, Per Person, Per Year, 2006-2019				
Barbour County	10,220,350	44				
Berkeley County	61,782,380	42				
Boone County	31,647,670	93				
Braxton County	10,467,910	52				
Brooke County	16,660,590	50				

Cabell County	108,311,280	81
Calhoun County	2,137,780	20
Clay County	4,359,750	33
Doddridge County	1,800,760	16
Fayette County	32,694,470	51
Gilmer County	3,567,529	31
Grant County	5,006,920	30
Greenbrier County	36,936,802	75
Hampshire County	9,410,140	29
Hancock County	36,156,750	85
Hardy County	6,191,340	32
Harrison County	71,480,870	75
Jackson County	18,781,692	46
Jefferson County	28,249,150	38
Kanawha County	171,793,360	64
Lewis County	11,197,450	49
Lincoln County	17,713,950	59
Logan County	70,586,560	141
Marion County	36,353,988	46
Marshall County	32,000,370	70
Mason County	23,668,720	63
McDowell County	23,232,100	78
Mercer County	54,029,540	63
Mineral County	15,573,320	40
Mingo County	48,395,250	132
Monongalia County	50,076,367	37
Monroe County	5,216,690	28
Morgan County	8,882,090	37
Nicholas County	31,464,860	87
Ohio County	28,908,590	47
Pendleton County	2,739,040	26
Pleasants County	5,691,210	54
Pocahontas County	4,336,540	36
Preston County	14,047,700	30
Putnam County	37,284,090	48
Raleigh County	82,858,360	76
Randolph County	20,071,980	49
Ritchie County	4,520,060	31
Roane County	8,495,430	41
Summers County	8,975,530	47
Taylor County	7,079,680	30
Tucker County	1,633,160	17
Tyler County	3,807,580	30
Upshur County	9,800,260	29
Wayne County	22,637,360	39
wayne County	22,037,300	37

Webster County	5,354,800	42
Wetzel County	13,038,260	57
Wirt County	1,567,610	19
Wood County	70,219,090	58
Wyoming County	29,336,680	90

- 606. As the volume of prescription opioids flooding into Plaintiffs' Communities increased, Plaintiffs each suffered harm and damages caused by the volume of opioids including abuse, addiction, overdose, and death, as well as other damages and harms such as emergency medical service responses for suspected overdoses, emergency department visits for overdose, naloxone administration prior to emergency medical services, increased burden on the treatment and chemical dependence provider system, OUD and opioid use among both adults and adolescents, and neonatal abstinence syndrome ("NAS").
- 607. As a result of the opioid epidemic, West Virginia has suffered and alarmingly high numbers of overdose deaths, including overdose deaths in each Plaintiff's Community. Between 2015 and 2018, every West Virginia county lost at least one resident to a drug overdose death with most suffering significantly more. Specifically, Plaintiffs' respective and associated counties suffered the following number of opioid-related overdose deaths between 2001 and 2023:

County	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20vtd	21vtd	22ytd	23vtd	24vtd
Barbour County	0	0	0	5	5	0	1-4	1-4	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	5	1-4	6	0
Berkeley County	6	7	18	13	16	11	19	21	32	20	32	28	47	39	47	89	89	67	57	108	87	87	64	13
Boone County	7	1-4	1-4	10	11	12	6	10	9	15	24	13	17	21	14	8	12	13	6	12	14	18	20	5
Braxton County	0	0	1-4	1-4	1-4	1-4	1-4	6	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	5	6	5	1-4
Brooke County	0	1-4	1 7	8		6	7	8	11	10	14	8	14	12	12	10	11	11	9	10	18	13	7	1-4
Cabell County	14	20	17	17	28	30	53	34	26	41	44	30	51	62	95	122	184	136	100	141	143	151	141	53
Calhoun County	0	1-4	0	0	1-4	0	0	0	1-4	1-4	1-4	1-4	1-4	1-4	0	0	1-4	0	0	0	0	1-4	1-4	0
Clay County	0	0	0	0	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	0	1-4	1-4	0	0	1-4	0	1-4	1-4	1-4	6	0
Doddridge County	0	0	0	0	0	1-4	0	0	0	1-4	1-4	1-4	1-4	0	1-4	1-4	1-4	0	1-4	1-4	0		1-4	1-4
Fayette County	6	6	1-4	7	9	11	18	9	11	14	21	15	19	16	15	13	19	16	17	25	35	43	32	11
Gilmer County	0	0	0	0	0	1-4	0	1-4	1-4	0	0	0	0	0	0	0	0	1-4	0	0	0	1-4	0	1-4
Grant County	0	0	1-4	1-4	0	0	0	1-4	1-4	1-4	1-4	1-4	1-4	0	1-4	1-4	1-4	5	1-4	1-4	5	1-4	1-4	1-4
Greenbrier County	5	0	7	9	8	9	8	9	1-4	10	11	9	6	10	10	7	1-4	9	5	17	23	22	24	1-4
Hampshire County	1-4	1-4	1-4	5	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	7	6	10	8	12	12	15	9	_	9	1-4
Hancock County	0	0	1-4	1-4	- 6	6	9	6	- 5	- 8	1-4	- 5	7	6	10	- 5	9	6	9	17	9		13	1-4
Hardy County	1-4	1-4	0	0	0	0	1-4	1-4	5	1-4	1-4	1-4	1-4	1-4	0	0	1-4	1-4	1-4	5	5	1-4	1-4	0
Harrison County	1-4	12	7	6	7	11	15	10	13	16	19	12	13	13	16	19	18	18	18	30	32	41	55	11
Jackson County	1-4	0	1-4	0	1-4	5	1-4	6	1-4	5	1-4	1-4	5	5	1-4	1-4	1-4	1-4	1-4	5	8	9	7	0
Jefferson County	1-4	5	1-4	6	7	7	8	11	10	11	7	10	13	11	13	30	27	22	17	27	21	31	21	1-4
Kanawha County	22	25	18	31	33	36	33	65	40	54	70	60	60	72	96	103	116	102	100	173	161	166	160	52
Lewis County	1-4	1-4	1-4	1-4	0	5	0	1-4	1-4	1-4	1-4	0	1-4	0	0	1-4	1-4	1-4	1-4	1-4	9	1-4	6	1-4
Lincoln County	1-4	1-4	1-4	1-4	1-4	8	6	1-4	1-4	8	10	1-4	6	8	6	6	9	5	6	9	16	17	17	13
Logan County	1-4	10	9	13	17	24	25	12	15	20	21	18	14	19	24	10	24	10	22	51	57	39	33	5
Marion County	9	5	5	9	14	11	21	24	18	25	19	11	16	7	22	8	9	10	7	25	33	32	35	13
Marshall County	1-4	1-4	1-4	6	- 5	8	11	5	7	5	8	5	1-4	1-4	6	7	10	5	8	27	31	33	24	9
Mason County	1-4	5	1-4	1-4	7	6	1-4	5	7	8	6	6	8	1-4	1-4	1-4	7	6	7	13	13	6	11	6
McDowell County	1-4	1-4	7	6	1-4	8	11	5	7	8	6	1-4	6	8	6	13	13	9	8	11	28	12	12	5
Mercer County	12	16	11	15	19	17	27	28	18	34	46	32	26	41	35	37	29	28	17	43	82	54	87	18
Mineral County	1-4	0	0	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	11	6	9	1-4	1-4	5	12	9	1-4
Mingo County	17	1-4	9	1-4	6	13	9	15	11	13	14	13	13	22	8	18	13	1-4	6	9	19	20	15	- 8
Monongalia County	1-4	7	7	8	9	9	10	14	11	10	9	19	11	18	23	41	37	32	36	63	63	62	63	17
Monroe County	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	7	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	6	1-4	1-4
Morgan County	1-4	1-4	7	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	7	9	1-4	1-4	1-4	10	11	6	9	11	7	7	1-4
Nicholas County	1-4	1-4	1-4	1-4	1-4	5	0	6	6	5	10	8	8	6	8	8	7	1-4	1-4	5	8	14	13	6
Ohio County	1-4	1-4	1-4	1-4	6	12	8	7	10	10	10	5	9	10	12	9	18	18	19	32	33	20	31	6
Pendleton County	0	1-4	1-4	1-4	0	1-4	0	1-4	1-4	0	0	0	0	0	0	0	0	1-4	0	1-4	0		1-4	0
Pleasants County	1-4	0	1-4	1-4	0	1-4	1-4	0	0	0	1-4	0	0	1-4	1-4	1-4	0	0	0	1-4	1-4	0	1-4	0
Pocahontas County	1-4	0	1-4	5	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	0	1-4	0	1-4	1-4	1-4	1-4	0
Preston County	0	0	1-4	0	1-4	5	1-4	1-4	1-4	1-4	1-4	5	1-4	5	1-4	5	1-4	1-4	5	1-4	12	10	14	0
Putnam County	1-4	1-4	1-4	7	6	8	7	9	6	9	13	6	7	7	9	12	28	18	12	19	11	16	11	1-4
Raleigh County		10	14	20	22	26	28	17	26	46	58	45	40	39	48	36	51	48	62	90	104	106	103	28
Randolph County	1-4	1-4	1-4	7	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	1-4	5	1-4	1-4	1-4	1-4	1-4	1-4	8	1-4
Ritchie County	1.4	0	1-4	1-4	1 4	0	0	0	0	1-4	1-4	1-4	1-4	1-4	0	0	1-4	1-4	1-4	1-4	1-4	0	1-4	0
Roane County	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	0
Summers County	1-4	1-4	1-4	1-4	1-4	1-4	5	5	1-4	9	6	8	1-4	1-4	1-4	7	5	1-4	1-4	12	12	1-4	8	1-4
Taylor County	1-4	1-4	1-4	1-4	1-4	1-4	1-4	6	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	5	1-4	1-4
Tucker County	1-4	0	1-4	0	1-4	0	0	0	0	0	0	1-4	0	0	0	0	0	1-4	0	0	1-4	1-4	1-4	0
Tyler County	1-4	0	1-4	0	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	0	1-4	1-4	0	0	1-4	1-4	1-4	1-4	1-4	0	0
Upshur County	0	1-4	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	1-4	5	6	6	6	0
Wayne County	- 0	1-4	1-4	7	12	1-4	8	1-4 5	7	1-4	1-4	7	1-4	1-4	1-4	27	33	23	23	35	27	27	23	1-4
Webster County	1-4	6	1-4	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	1-4	0	1-4	1-4	0	1-4	1-4	0
Wetzel County	1-4	0	1-4	1-4	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	5	1-4	1-4	6	7	8	1-4	1-4
Wirt County	1-4	1-4	0	1-4	1-4	0	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	1-4	0	1-4	1-4	0	1-4	1-4	1-4 5	1-4
Wood County	1-4	1-4	8	7	9	13	1-4	12	10	8	1-4	17	13	24	21	39	17		27	30	1-4 54	37	44	
Wood County Wyoming County	1-4	1-4	8	8	9	13	10	12	10	23	16 26	16	13	13	21 17	39 12	1/	28 9	6	30 15	19	26	23	16 5
w young county	1-4	1-4	/	8	8	11	10	19	11	23	26	10	9	13	1/	12	5	9	ь	15	19	20	23	5

- 608. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive.
- 609. Opioid overdose deaths are only one consequence of the opioid epidemic. Opioid abuse and addiction also causes increased emergency room visits, inpatient hospitalizations, and emergency medical technicians' administration of naloxone, the antidote to opioids, which Plaintiffs' Communities are each enduring as a result of the opioid epidemic.
- 610. As a result of the increase in overdoses, Plaintiffs' Communities have also sustained high costs related to emergency medical care and first responders.

- 611. Express Scripts' conduct has also had a significant effect on the increase of crime and related criminal justice expenses within Plaintiffs' Communities.
- 612. While Express Scripts was reaping millions of dollars in profits from their wrongful conduct, Plaintiffs have been required to allocate substantial public monies and resources to combat the opioid crisis and cope with its fallout.
- 613. Plaintiffs have incurred and continue to incur substantial costs because of Express Scripts' conduct including, but not limited to, costs of increased services with respect to law enforcement and first responders; county health facilities, including clinics; detention centers and jails; county courts, including drug courts; education programs; community outreach programs; equipment and supplies; victim services supports; drug abuse prevention and education programs; inmate services including housing, health and support staff; intervention programs; and increased costs associated with its own employee benefits plan, together with general societal and lost productivity costs and costs to repair and restore County infrastructure and services.
- 614. Plaintiffs have had to allocate or re-allocate extraordinary resources through staffing at departments providing all of the services listed above; have incurred substantial increases in overtime and related costs associated with educational and judicial support services.

X. Plaintiffs' Claims Are Timely.

- 615. The opioid epidemic continues today in Plaintiffs' Communities and Plaintiffs continue to suffer harm and damages from the wrongful conduct of Express Scripts.
- 616. The wrongful conduct of Express Scripts has caused a repeated or continuous injury. The harm and damages caused by Express Scripts' conduct have not occurred all at once, but have occurred over time and continue to occur. Express Scripts' tortious conduct has not ceased, and its consequences are not completed, nor have all Plaintiffs' damages yet been incurred from Express Scripts wrongful conduct.

- 617. The public nuisance caused by Express Scripts' wrongful conduct remains unabated.
- 618. Express Scripts' wrongful conduct which caused the opioid epidemic and continues to cause Plaintiffs' damages remains unabated.
- 619. Plaintiffs neither knew nor should have reasonably known by the exercise of reasonable diligence of Express Scripts' wrongful conduct, or that substantial, non-transient damage had resulted and was capable of ascertainment as result of Express Scripts' conduct.
- 620. Plaintiffs did not learn they had been injured by Express Scripts' actions, the source of those injuries, or that those injuries were part of a pattern of conduct until only recently when documents revealing those facts were produced in discovery by various entities in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804-DAP (N.D. Ohio) and other opioids litigation, including the documents cited, quoted, and relied on throughout this Complaint. These documents—and the facts they contain—have never before been made public, nor have they ever before been in Plaintiffs' possession, and have not otherwise been available to Plaintiffs before being produced in discovery. Thus, any applicable limitations period did not begin to run when Express Scripts committed its wrongful acts, but when Plaintiffs knew, or by the exercise of reasonable diligence, should know (1) that they have been injured, (2) the identity of the entity who owed Plaintiffs a duty to act with due care, and who may have engaged in conduct that breached that duty, and (3) that the conduct of that entity has a causal relation to the injury—which could not have occurred until the documents revealing those facts were produced in discovery.
- 621. Express Scripts is equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to purposefully conceal their wrongful conduct and deceive Plaintiffs.

- 622. Express Scripts undertook efforts, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, to purposefully conceal its wrongful conduct by: (1) manipulating and distorting public information, knowledge, and facts; (2) misrepresenting their role in the pharmaceutical market as promoting safe use and appropriate opioid dispensing; (3) assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse; (4) hiding the true nature of their relationships with the Opioid Manufacturers; (5) failing to make public or otherwise produce nonpublic information, over which Express Scripts had exclusive possession, dominion, and control, that would have revealed the truth; (6) entering into overly broad confidentiality agreements with any entity in the supply chain with whom they contracted; (7) suing governmental and other entities to block the release of details in their agreements with the Opioid Manufacturers and pharmacies; and (8) by deliberately and fraudulently concealing the truth.
- 623. Express Scripts fraudulently concealed from Plaintiffs the existence of Plaintiffs' causes of action. Express Scripts' public misrepresentations about its role in the pharmaceutical market, and that it was ensuring the safe use and appropriate opioid dispensing, and preventing diversion and drug abuse, prevented Plaintiffs from investigating Express Scripts' fraud.
- 624. Express Scripts also concealed from Plaintiffs the existence of Plaintiffs' claims by misrepresenting to the public, as well as to its clients, that it used its market power to create formularies and UM programs based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. As alleged herein, Express Scripts repeatedly represented that it was working to ensure that opioids were prescribed and dispensed only for safe and legitimate reasons. These misrepresentations were made in person, in client contracts, on Express Scripts' websites, in publications and in Congressional testimony. Express Scripts told

the public, its clients and Congress that it was an expert who was committed to preventing and addressing misuse, abuse, and diversion of prescription opioids.

- 625. Express Scripts and its mail order pharmacies hid from their clients, patients, regulators and Plaintiffs: (a) the fraudulent nature of its relationship with the Opioid Manufacturers; (b) the fraudulent nature of its representations; (c) its intention to ignore its contractual cDUR obligations; (d) its intent to make formulary and Utilization Management decisions that failed to limit the medically unnecessary and inappropriate prescribing, sales, or dispensing of prescription opioids or address misuse, abuse, and diversion; and (e) the true nature of the association between each member of each PBM Enterprise.
- 626. Plaintiffs did not discover the nature, scope and magnitude of Express Scripts' misconduct, and its full impact on Plaintiffs and their respective communities, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.
- 627. Express Scripts intended that its actions and omissions would be relied upon, including by Plaintiffs and Plaintiffs' Communities. Plaintiffs and Plaintiffs' Communities did not know and did not have the means to know the truth, due to Express Scripts' actions and omissions.
- 628. Plaintiffs and Plaintiffs' Communities reasonably relied on Express Scripts' affirmative statements alleged herein, including those regarding Express Scripts' commitment to preventing and addressing the misuse, abuse, and diversion of opioids.

XI. Successor Liability

629. To the extent that the wrongful acts or omissions alleged herein where committed or omitted by predecessor entities, their respective successor entities are liable for those acts or omissions because (1) they expressly or impliedly assumed the predecessor's liability, (2) there was a consolidation or merger of predecessor and successor, (3) the surviving entity was a mere continuation of the predecessor or (4) when the transaction is entered into fraudulently to escape

liability for the debts and liabilities. To the extent there was no formal merger of predecessor and successor, the respective successor entities are also liable for the wrongful acts or omissions of their respective predecessors based on the doctrine of de facto merger based on the factors of (a) continuity of shareholders resulting from the purchasing corporation paying for the assets with shares of its own stock so the selling corporation stockholders become a constituent part of the purchasing corporation; (b) cessation of ordinary business and dissolution of the predecessor; (c) assumption by the successor of liabilities ordinarily necessary for the uninterrupted continuation of the business of the predecessor; and (d) continuity of management, personnel, and general business operation of the predecessor. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiffs without discovery.

XII. Alter Ego Liability

- or omitted by wholly-owned or majority-owned entities, the parent entities are liable for those acts or omissions as alter egos because (1) they dominated and controlled the wholly-owned or majority-owned entity and (2) exercised that domination and control to perpetrate a wrong or injustice. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiffs without discovery.
- XIII. Express Scripts' Conduct Was Carried Out With Actual Malice And With a Conscious, Reckless and Outrageous Indifference to the Health, Safety and Welfare of Plaintiffs, Plaintiffs' Communities and the Citizens of West Virginia.
- 631. Express Scripts' conduct as described in this Complaint was carried out with actual malice towards Plaintiffs and with a conscious, reckless and outrageous indifference to the health, safety and welfare of Plaintiffs, Plaintiffs' Communities, and the citizens of West Virginia.

- 632. Express Scripts conduct as described herein was knowing, intentional, and deliberate and carried out with the intent to increase the sales of, and profits from, dangerous opioid drugs at the expense of the health, safety, and welfare of Plaintiffs and Plaintiffs' Communities.
- 633. By engaging in the wrongful conduct described herein above, Express Scripts engaged in willful misconduct and exhibited an entire want of care that rises to the level of actual malice and/or a conscious, reckless and outrageous indifference to indifference to the health, safety and welfare of the Plaintiffs, Plaintiffs' Communities and others.
- 634. Express Scripts' actions demonstrated both malice and also aggravated and egregious fraud. Express Scripts engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm.

XIV. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Common Law Public Nuisance

- 635. Plaintiffs repeat, re-allege, and incorporate each and every allegation set forth in all other paragraphs of this Complaint, as if fully set forth herein, and further alleges as follows:
- 636. Express Scripts intentionally and/or negligently and recklessly caused, created, contributed to, and/or maintained a public nuisance which proximately caused injury to Plaintiffs and interfered with public rights, including the public rights to health and safety, in each Plaintiff's Community.
- 637. Express Scripts is liable for the public nuisance because its conduct has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to the harm in Plaintiffs' Communities and Plaintiffs' injuries and damages. *See* Restatement Second, Torts §821B.

- 638. Express Scripts, by colluding with opioid manufacturers to make prescription opioids more available and ignoring evidence of addiction, abuse and diversion within their own prescription claims data and/or other actions and inactions described herein, caused, created and/or maintained a public nuisance in each Plaintiff's Community in the form of an opioid epidemic, which caused, and continues to cause, harm and disruption to, and unreasonably annoys, injures, endangers, and interferes with the public health, public safety, public peace, public comfort, and/or public convenience of Plaintiffs' Communities. The public nuisance caused by Express Scripts has significantly harmed, and continues to significantly harm, each Plaintiff and a considerable number of the residents of the Plaintiffs' Communities.
- 639. Express Scripts gathered enormous amounts of data about the opioid prescriptions and opioid-related claims of their members in this Judicial District, Plaintiffs' Communities, and throughout the State. Express Scripts used this data to enhance its profitability but opted not to use it to inform their marketing practices, identify and prevent diversion, or identify and prevent the dispensing and sale of unreasonably large quantities of prescription opioids, and "cocktails" of opioids and other drugs, in Plaintiffs' Communities and in West Virginia.
- 640. Express Scripts caused and maintained a public nuisance in Plaintiffs' Communities through their ongoing intentional and/or negligent and reckless and/or unlawful conduct, including, but not limited to: undertaking to administer prescription drug benefits and dispensing in the public interest and in conformity with public health and safety, and then electing not to (and/or failing to) appropriately carry out these obligations; fraudulently and/or falsely promoting the use of opioids for conditions and in circumstances where they are neither safe nor effective; misrepresenting to the public and the medical community that opioids could be taken at high doses and for long durations with minimal risk of addiction; electing not to (and/or failing to)

use the wealth of data available to them to identify and address signs of over-prescribing, illegitimate and dangerous use of opioids, misuse, abuse, and diversion; facilitating and encouraging the use of dangerously addictive opioids by colluding with manufacturers to place opioid drugs on standard formulary offerings with preferred status; declining to impose limits on their approval for use of opioids in exchange for payments and fees from manufacturers; electing not to (and/or failing to) provide controls against diversion in their PBM services; and violating the Controlled Substances Act, and West Virginia controlled substances and pharmacy laws and regulations, by failing to detect and guard against diversion when dispensing opioids, and "cocktails" of opioids and other drugs, through their mail order pharmacies, and in their provision of PBM services. Express Scripts' wrongful conduct caused prescriptions and sales of opioids to skyrocket in West Virginia, this Judicial District, and Plaintiffs' Communities, and Express Scripts failed to limit their use even as evidence of the epidemic mounted, including in Plaintiffs' Communities, flooding Plaintiffs' Communities with opioids and facilitating and encouraging the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs as well as Plaintiffs' Communities.

- 641. Express Scripts knew, or were substantially certain, or reasonably should have known, that its intentional and/or negligent, unreasonable, reckless, and/or unlawful conduct would and did cause opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has, and will continue to have, a detrimental and unreasonable effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and Plaintiffs' Communities.
- 642. Express Scripts' conduct has injuriously affected rights common to the general public, specifically including the rights of people in Plaintiffs' Communities to public health,

safety, peace, comfort, and convenience. The public nuisance caused by Express Scripts' conduct has caused substantial annoyance, inconvenience, and injury to the public.

- 643. The interference is unreasonable because Express Scripts' nuisance-creating conduct:
 - (a) Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;
 - (b) At all relevant times was and is proscribed by state and federal laws and regulations; and/or
 - (c) Is of a continuing nature and, as Express Scripts knows, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.
- 644. The significant interference with rights common to the general public is described above and includes but is not limited to:
 - (a) The creation and fostering of an illegal, secondary market for prescription opioids;
 - (b) Easy access to prescription opioids by children and teenagers;
 - (c) A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;
 - (d) Infants being born dependent on, or addicted to, opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
 - (e) Employers having lost the value of productive and healthy employees; and
 - (f) Increased costs and expenses for Plaintiffs relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.
- 645. Express Scripts knowingly, intentionally, recklessly, negligently, and/or unlawfully pushed as many prescription opioids, and "cocktails" of opioids and other drugs, onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of each

Plaintiff's Community, a higher level of fear, discomfort and inconvenience to Plaintiffs' Communities, and direct costs to Plaintiffs and Plaintiffs' Communities.

- 646. Express Scripts is liable for creating the public nuisance because the intentional and/or negligent, and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in causing the public nuisance and harm to Plaintiffs and Plaintiffs' Communities.
- 647. At all relevant times, Express Scripts was (or reasonably should have been) aware of, and understood, its legal obligations under the federal Controlled Substances Act (21 U.S.C. § 801, et seq.), the West Virginia Controlled Substances Act, W.Va. Code C.S.R. § 15-2-1, et seq., and applicable West Virginia pharmacy laws and regulations regarding the dispensing of prescription opioids.
- 648. In its sale and dispensation of opioids, and "cocktails" of opioids and other drugs, in this District and in each Plaintiff's Community, Express Scripts violated federal law, including, but not limited to, 21 U.S.C.A. §§ 829, 841, 842 and 21 C.F.R. §§ 1301.71, 1306.04, 1306.06, and West Virginia law, including, but not limited to, W. Va. C.S.R. § 15-2-3 (previously W.Va. C.S.R. § 15-2-2), W. Va. C.S.R. § 15- 2-4, W.Va. C.S.R. § 15-2-4.4, W.Va. C.S.R. § 15-2-4.5, W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1), W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4), W.Va. Code § 60A-4-401(a), W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); and W. Va. Code § 60A-3-308(d)(I). Express Scripts' violations of these laws were committed knowingly and/or negligently and recklessly.
- 649. Each of the aforementioned statutes violated by Express Scripts establish specific requirements for the protection of others.

- 650. Express Scripts' intentional (and/or negligent and reckless), unlawful, and unreasonable conduct that created, continued, and/or maintained the public nuisance in Plaintiffs' Communities, for which the gravity of the harm outweighs the utility of the conduct, is described herein and includes, but is not limited to:
 - (a) Knowingly and intentionally (and/or negligently and recklessly) colluding with the prescription opioid manufacturers in deceptive marketing schemes that were designed to, and successfully did, change the perception of opioids and cause opioid prescribing and sales to skyrocket;
 - (b) Knowingly and intentionally (and/or negligently and recklessly) facilitating the increased use of opioids by giving opioids unwarranted preferred formulary status in standard offerings in exchange for profiting from payments from the prescription opioid manufacturers;
 - (c) Intentionally (and/or negligently and recklessly) maintaining preferred formulary status for OxyContin and other highly abused opioids in standard offerings, despite knowing, or being substantially certain, from their own extensive data, that addiction, abuse, and illegitimate prescribing of such drugs were rampant;
 - (d) Deliberately (and/or negligently and recklessly) electing not to undertake timely actions utilizing their real-time data that would have drastically reduced the inappropriate prescribing and dispensing of Opioids, such as requiring prior authorization, step therapy, limiting days of supply, or excluding OxyContin from its standard formulary offerings;
 - (e) Deliberately (and/or negligently and recklessly) electing not to impose prior authorization requirements or limits on the availability of opioids in its standard formulary offerings in exchange for payments from the prescription opioid manufacturers;
 - (f) Deliberately (and/or negligently and recklessly) electing not to maintain adequate safeguards to dispense opioids in a safe and effective manner and to maintain effective controls against diversion of opioids through their mail-order pharmacies; and
 - (g) Deliberately (and/or negligently and recklessly) electing not to report suspicious prescribers and pharmacies.
- 651. When Express Scripts engaged in this conduct, it knew, or were substantially certain, or reasonably should have known, that, *inter alia*: (i) increasing the availability of

prescription opioids would increase the number of opioids that would be abused, misused, and diverted into the illegal, secondary market and would be obtained by persons with criminal purposes; (ii) the marketing by manufacturers with which they colluded was deceptive and that Express Scripts' conduct served to increase opioid sales; (iii) many of the opioid prescriptions they

dispensed, or facilitated the dispensing of, were not issued for a legitimate medical purpose and

were likely to be diverted; and (iv) by failing to act reasonably and lawfully with respect to the

sale and dispensing of opioids, and "cocktails" of opioids and other drugs, and by participating in

the false marketing of opioids, in Plaintiffs' Communities, diversion and the associated harms and

resulting interference with public health, safety, and welfare would occur.

- 652. At all relevant times, Express Scripts knew or reasonably should have known that prescription opioids were dangerous because, *inter alia*, these drugs are defined under federal and state law, and are generally recognized, as substances posing a high potential for abuse, addiction, and death.
- 653. Indeed, prescription opioids are essentially medical grade heroin. Express Scripts' wrongful and unreasonable conduct of pushing as many opioids, and "cocktails" of opioids and other drugs, onto the market as possible led directly to the public nuisance and harm to Plaintiffs—exactly as would be expected when medical-grade heroin in the form of prescription opioids flood the community and are diverted into an illegal, secondary market.
- 654. Express Scripts knows, and has known, that its intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and Plaintiffs' Communities.

- 655. It was reasonably foreseeable to Express Scripts that its conduct would result in the public nuisance and unreasonable harm described herein to Plaintiffs and Plaintiffs' Communities.
- 656. Express Scripts owes Plaintiffs and the public a duty to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This includes a duty to not create a foreseeable risk of harm or injury.
- 657. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Express Scripts' conduct in selling, delivering, dispensing, promoting, and gatekeeping control of the supply of highly addictive and dangerous opioids requires a high degree of care and places them in a position of great trust and responsibility. Their duty cannot be delegated.
- 658. Express Scripts, by promoting opioid over-use and by facilitating access to opioids through their standard formulary and UM offerings and their mail-order pharmacies, set in motion a force that created an unreasonable and foreseeable risk of harm for Plaintiffs and Plaintiffs' Communities.
- 659. Express Scripts also undertook and assumed a duty to create a standard formulary and UM offerings based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. *See* Restatement (Second) of Torts § 324A. Express Scripts represented to the public, as well as to their clients, that they were structuring their standard formulary and UM offerings based on the health and safety of the public and the lives their clients insured, when in fact they were doing the exact opposite and doing it to maximize their own revenue in concert with the opioid manufacturers. Express Scripts knew, at the time that they made these representations to the public and to their clients, that they would not base their formulary and

UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that they would make, and were already making, formulary and utilization management decisions designed solely (or at least primarily) to increase profits to Express Scripts.

- 660. Express Scripts undertook to render services which it should have recognized (and in fact did know) were necessary for the protection of persons, including the public, Plaintiffs, and Plaintiffs' Communities, and failed to exercise reasonable care such that it increased the risk of harm to the public, Plaintiffs' Communities, and Plaintiffs. In so undertaking, Express Scripts assumed a duty to the public, Plaintiffs, and Plaintiffs' Communities.
- 661. Express Scripts knew or reasonably should have known of the over-use and over-supply of opioids because of their access to claims and other data which they developed and maintained. Express Scripts also had the ability to curtail the over-use and over-supply of prescription opioids because of their unique gatekeeping function in the pharmaceutical supply chain. Yet, despite this knowledge and ability, Express Scripts refused and failed to take necessary and appropriate actions to prevent the harms which were the foreseeable consequence of their failures, actions, and inactions.
- 662. Express Scripts, having facilitated and set in motion the over-use and over-supply of prescription opioids, had a duty to use reasonable care to prevent and curtail the spreading of the opioid epidemic.
- 663. Express Scripts breached this duty by failing to exercise reasonable care or skill with respect to their opioid-related conduct. Collectively and individually, Express Scripts made highly addictive prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger especially to patients who were using opioids for chronic pain not associated with active cancer, end-of-life or

palliative care. Express Scripts knew or reasonably should have known that its breach would foreseeably cause harm to Plaintiffs and Plaintiffs' Communities.

- 664. Express Scripts was negligent in failing to abide their duties to conduct themselves with the requisite care and skill and faithfulness.
- 665. Express Scripts placed its profit motives above their legal duties and enabled, encouraged, and caused the over-use and over-supply of opioids in this this Judicial District and in Plaintiffs' Communities.
- 666. Express Scripts is a highly sophisticated and knowledgeable actor in the health care marketplace, well informed of the highly addictive nature of prescription opioids and likelihood of foreseeable harm to Plaintiffs' Communities from opioid addiction and diversion. Express Scripts breached its duties when it failed to act with reasonable care in its respective role which positioned it in a unique position to prevent and help abate the opioid epidemic if they had elected to do so, instead of profit.
- 667. Violating these duties poses distinctive and significant dangers to Plaintiffs and Plaintiffs' Communities.
- 668. Express Scripts knew or in the exercise of reasonable diligence should have known under the circumstances of this case that the public nuisance and harms suffered by Plaintiffs and Plaintiffs' Communities were the reasonably foreseeable consequences of Express Scripts' failures, actions, and inactions.
- 669. It was also reasonably foreseeable to Express Scripts that its conduct would create a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Express Scripts' deceptive and improper conduct is not only

an explosion of prescription opioids on the black market, but also—predictably and foreseeably—a marked increase in the availability of heroin and synthetic opioids.

- 670. The health, safety, and welfare of Plaintiffs' Communities, including those residents within who use, have used, or will use prescription opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to Plaintiffs' Communities. It was reasonably foreseeable to Express Scripts that the burden of the opioid crisis would fall to Plaintiffs' Communities in the form of social and economic costs.
- 671. The public nuisance created by Express Scripts' intentional, negligent, and/or reckless and/or unlawful conduct is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs and Plaintiffs' Communities, and the harm inflicted greatly outweighs any offsetting benefit.
- 672. The injuries to Plaintiffs and Plaintiffs' Communities would not have happened in the ordinary course of events had Express Scripts exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business in the sale, delivery, dispensing, promotion, and gatekeeping control of opioids.
- 673. Express Scripts' conduct is widespread and persistent and creates substantial and ongoing harm. The harm inflicted outweighs any offsetting benefit. Express Scripts' conduct has caused abuse, addition, overdoes, deaths, serious injuries, and a severe disruption of public peace, health, order and safety. Express Scripts' ongoing and persistent misconduct is producing permanent and long-lasting damage in Plaintiffs' Communities.
- 674. Express Scripts' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Plaintiffs' Communities. Because of Express Scripts' actions in using its unique position to increase the availability of opioids in the

marketplace and inflate opioid sales, because of its collusion with manufacturers in the deceptive marketing of opioids, and because of Express Scripts' special position within the closed system of opioid distribution, without Express Scripts' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid, heroin and fentanyl overuse, abuse, and addiction that now exists would have been averted.

- 675. Express Scripts had control over their conduct in and affecting Plaintiffs' Communities as is described herein, and that conduct has had a severely adverse effect on the public. Express Scripts had sufficient control over, and responsibility for, the public nuisance it created. Express Scripts was in control of the "instrumentality" of the nuisance, namely the dissemination of prescription opioids, their collusion with manufacturers in promoting opioids, and standard formulary placement and drug utilization management offerings that increased utilization of opioids as described herein.
- 676. Plaintiffs do not allege that the opioid drugs are inherently defective, nor that the FDA-approved warning labels are inadequate, and Plaintiffs do not seek a remedy under theories of product defect or failure to warn.
- 677. Express Scripts acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.
- 678. Express Scripts' scheme to optimize profits and opioid utilization regardless of the harm that was substantially certain to occur to Plaintiffs and Plaintiffs' Communities was done knowingly and intentionally and/or negligently and recklessly.
- 679. But for Express Scripts' actions, opioid use—and, ultimately, misuse and abuse—would not be as widespread as it is today, and the opioid epidemic that currently exists would have been averted or greatly curtailed.

- 680. As a direct and proximate cause of Express Scripts' intentional and/or negligent and reckless and/or unlawful conduct in creating or assisting in the creation of a public nuisance, Plaintiffs and Plaintiffs' Communities have sustained and will continue to sustain substantial harm, injuries, and damages.
- 681. Plaintiffs have standing to bring claims for public nuisance under West Virginia law to abate a public nuisance.
- 682. Plaintiffs bring this action to promote the public welfare, for the benefit of all who live in and around Plaintiffs' Communities and the public generally.
- 683. In addition, Plaintiffs have sustained injury and damages to their property and resources because of the public nuisance described herein.
- 684. Express Scripts' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.
- 685. Express Scripts' misconduct alleged in this Complaint is ongoing and persistent, as is the nuisance to which it substantially contributed.
- 686. As a direct and proximate result of Express Scripts' intentional and/or negligent and/or reckless and/or unlawful conduct and the public nuisance created by Express Scripts, Plaintiffs and Plaintiffs' Communities have incurred, and will continue to incur, excessive costs to treat the opioid epidemic including, but not limited to, increased costs of police, emergency, health, prosecution, corrections, rehabilitation, and other services. These costs are over and above ordinary public services.

- 687. As a direct and proximate result of Express Scripts' intentional and/or negligent and reckless conduct and the public nuisance created by Express Scripts, public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which would otherwise be used to serve the public at large in Plaintiffs' Communities.
- 688. Plaintiffs seek to abate the nuisance created by Express Scripts' unreasonable, unlawful, intentional, unlawful and/or negligent, reckless, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.
- 689. In doing so, Plaintiffs are asserting their own rights and interests and Plaintiffs' claims are not based upon or derivative of the rights of others.
- 690. The public nuisance in each Plaintiff's respective Community—i.e., the opioid epidemic—created, perpetuated, and maintained by Express Scripts—can be abated and further recurrence of such harm and inconvenience can be prevented. However, Express Scripts lack the infrastructure and expertise needed to abate the public nuisance it created, contributed to, and/or maintained in Plaintiffs' Communities. Express Scripts' conduct—including its lack of regard for the well-being of Plaintiffs' Communities by elevating its own business interests and profit over the safety and health of the communities in which prescription opioids were marketed, promoted, dispensed, and sold—also renders it unfit to oversee the abatement of the public nuisance it created, contributed to, and/or maintained.
- 691. Plaintiffs seek a judgment that Express Scripts fund the abatement of the ongoing public nuisance caused by their unreasonable, unlawful, intentional, unlawful and/or negligent, reckless, ongoing, continuing, and persistent actions and omissions and its substantial and unreasonable interference with rights common to Plaintiffs' Communities and the general public.

- 692. Express Scripts created or assisted in creating the opioid epidemic, and Express Scripts is jointly and severally liable for its abatement. Furthermore, Express Scripts should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in Plaintiffs' Communities. Additionally, Express Scripts should compensate Plaintiffs for the funds they have expended and continue to expend for increased costs of, *inter alia*, social services, health systems, law enforcement, judicial system, and treatment facilities.
- 693. Plaintiffs have suffered, and will continue to suffer, unique harms as described herein, which are of a different kind and degree than those suffered by the public in general. These are harms that can only be suffered by Plaintiffs.
- 694. Plaintiffs are acting in their governmental capacity to vindicate the rights of the public and abate a public nuisance within their communities. Their claims are not based upon or derivative of the rights of others.
- 695. The tortious and unlawful conduct of Express Scripts was a substantial factor in causing the opioid epidemic, the opioid public nuisance, and harm to Plaintiffs and Plaintiffs' Communities.
- 696. Plaintiffs and Plaintiffs' Communities have suffered an indivisible injury as a result of the tortious conduct of Express Scripts.
- 697. Express Scripts' conduct was intentional, willful, wanton, unlawful and/or reckless and was directed at the public generally, constituted a gross and wanton fraud upon the public. Express Scripts acted with actual malice and a conscious, reckless and outrageous indifference to the health, safety and welfare of Plaintiffs and Plaintiffs' Communities and the State of West Virginia. Accordingly, punitive damages are warranted and justified in this case.

- 698. Express Scripts' conduct was wanton in that it was committed with reckless disregard of the Plaintiffs' and the public's rights or the consequences of said conduct.
- 699. Express Scripts acted with malice. It specifically intended to cause substantial injury or harm to Plaintiffs and Plaintiffs' Communities because it either desired to cause the consequences of its actions or omissions, or believed that the consequences were substantially certain to result from its actions or omissions. Specifically, Express Scripts knew that its conduct was resulting in, or was substantially certain to result in, an unreasonable and substantial interference with the public health, welfare, and safety in Plaintiffs' Communities.
- 700. Express Scripts' conduct was fraudulent. It acted in concert with prescription opioid manufacturers to promote false and fraudulent messaging about the treatment of pain and the addictive nature of opioids. Express Scripts also created false and misleading impressions to regulators, prescribers, their clients, and the public, that it rigorously carried out it legal duties, including its duty to implement effective controls against diversion and to exercise due diligence to prevent the dispensing of opioid prescriptions that are illegitimate and/or likely to be diverted. Express Scripts further created the false impression that it worked voluntarily to prevent opioid abuse, misuse, oversupply, and diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.
- 701. At all times alleged herein, Express Scripts had actual, subjective awareness that, viewed objectively from its viewpoint at the time, its conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Express Scripts knew of the dangerous and addictive nature of prescription opioids and also knew the risks associated with the oversupply and diversion of such drugs. Yet it nevertheless proceeded with conscious

and/or reckless indifference to the rights, safety, or welfare of Plaintiffs and Plaintiffs' Communities by and through their conduct described herein.

702. Plaintiffs seek all legal and equitable relief as allowed by law for the intentional and/or negligent creation of a public nuisance, including, *inter alia*, injunctive relief, abatement, compensatory and exemplary/punitive damages, and all other damages allowed by law to be paid by Express Scripts, attorneys' fees and costs, pre- and post-judgment interest, and such other relief as this Court deems appropriate.

SECOND CLAIM FOR RELIEF

Violation Of Federal Civil Rico, 18 U.S.C. 1961, et seq.; 1964(C)

- 703. Plaintiffs repeat, re-allege, and incorporate each and every allegation set forth in all other paragraphs of this Complaint as if fully set forth herein.
- 704. At all relevant times, Express Scripts was a "person" under 18 U.S.C. § 1961(3) because they were both capable of holding, and do hold, legal or beneficial interests in property.
- 705. As alleged more fully herein, Express Scripts formed an association-in-fact enterprise with each of the Opioid Enterprise Manufacturers, described above as the Formulary & UM Enterprise, for the purpose of carrying out a fraudulent scheme and felonious possession and dispensing of controlled substances to maximize profits for themselves and the Opioid Enterprise Manufacturers from increasing sales of prescription opioids through unfettered and preferential formulary access without UM in Express Scripts' standard offerings, despite Express Scripts' promises, representations and contractual obligations to take actions, including through cDUR, formulary decisions and UM decisions that were in their clients' best interests, to ensure safe and medically appropriate opioids were being dispensed, and to address opioid abuse, misuse and diversion.

- 706. As alleged more fully herein, the Formulary & UM Enterprise consisted of personal business relationships formed through contractual negotiations over decades and participation in and through the PCMA and other informal coalitions and working groups. Evidence of the existence of the Formulary & UM Enterprise can be found in the way Express Scripts took nearly identical action towards formulary and UM offerings compared to other PBMs, in the research Express Scripts performed for the Opioid Enterprise Manufacturers, the contracts it negotiated with the Opioid Enterprise Manufacturers that gave it preferential formulary positions prohibited the implementation of UM, pull-through marketing and PBM data exchange, failure to comply with the dispensing requirements of the CSA and West Virginia law, and interactions through PCMA and other informal coalitions.
- 707. At all relevant times, the Formulary & UM Enterprise (a) had an existence separate and distinct from each of the members; (b) was separate and distinct from the pattern of racketeering in which the members engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the members; (d) was characterized by interpersonal business relationships among the members; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as continuing units.
- 708. Each member of the Formulary & UM Enterprise conducted, and participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits.
- 709. Express Scripts carried out, or attempted to carry out, a scheme to defraud by knowingly conducting and participating in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that made use of the mail and wire facilities in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

- 710. Express Scripts committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Formulary & UM Enterprise members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Formulary & UM Enterprise members' regular use of the facilities, services, distribution channels, and employees of the Formulary & UM Enterprise. Express Scripts participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.
- 711. Express Scripts also conducted and participated in the conduct of the affairs of the Formulary & UM Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in controlled, punishable under any law of the United States.
- 712. Express Scripts committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 841 makes it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance except as authorized by Subchapter I of the CSA. A violation of § 841 in the case of controlled substances on Schedule II is punishable by not more than 20 years of imprisonment, or not less than 20 years imprisonment if death or seriously bodily injury results from the use of such substance. Similarly, a violation of § 841 in the case of controlled substances on Schedule III is punishable by not more than 10 years imprisonment, or not less than

¹⁹⁸ 21 U.S.C. § 841(b)(1)(C).

15 year imprisonment if death or seriously bodily injury results from the use of such substance. ¹⁹⁹ Similarly, a violation of § 841 in the case of controlled substances in Schedule IV is punishable by note more than 5 years imprisonment. ²⁰⁰ All three violations of § 841 are felonies.

- 713. Each of Express Scripts' mail order pharmacies are registrants as defined in the CSA. Their status as registrants imposes obligations on them to ensure that they only dispense "to the extent authorized by their registration and in conformity with the [CSA].²⁰¹
- 714. Express Scripts registered their mail order pharmacies with the DEA to dispense Schedule II-V controlled substances. Their DEA registrations only authorized Express Scripts' owned pharmacies to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner."²⁰²
- 715. The Formulary & UM Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:
 - (a) Mail Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise.
 - (b) Wire Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise.

¹⁹⁹ 21 U.S.C. § 841(b)(1)(E).

²⁰⁰ 21 U.S.C. § 851(b)(2).

²⁰¹ 21 U.S.C. § 822(b).

²⁰² 21 U.S.C. § 802(10); 21 U.S.C. § 829(a)-(b) (stating no Schedule II, III or IV drug may be dispensed without the written prescription of a practitioner, and that no Schedule V drug may be dispensed other than for a medical purpose); *accord* 21 U.S.C. § 823(f)

- (c) Felony Controlled Substance Violations: Express Scripts violated 21 U.S.C. § 841 by knowingly or intentionally possessing and dispensing controlled substances for reasons and purposes not authorized by the Controlled Substance Act.
- 716. The Formulary & UM Enterprise conducted their pattern of racketeering activity in this jurisdiction and throughout the United States.
- 717. The Formulary & UM Enterprise aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses, and the 21 U.S.C. § 841 offense.
- 718. The members of the Formulary & UM Enterprise, with knowledge and intent, agreed to the overall objective of the Formulary & UM Enterprise, including the fraudulent scheme and felonious possession and dispensing of controlled substances, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing, distributing, and dispensing prescription opioids.
- 719. Indeed, for the Formulary & UM Enterprise's fraudulent scheme to work, each member of the Formulary & UM Enterprise had to agree to implement their necessary portion of the Formulary & UM Enterprise's activities in the manner alleged above.
- 720. As alleged more fully herein, the Formulary & UM Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts were each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 721. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-

dollar revenue and profits for the Formulary & UM Enterprise. The predicate acts were conducted by members of the Formulary & UM Enterprise and in furtherance of its fraudulent scheme.

- 722. The pattern of racketeering activity alleged more fully herein, and the Formulary & UM Enterprise are separate and distinct from each other. Likewise, Express Scripts are distinct from the Formulary & UM Enterprise.
- 723. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.
- 724. Many of the precise dates of the Formulary & UM Enterprise's actions at issue here have been hidden by Express Scripts and the members of the Formulary & UM Enterprise and cannot be alleged without complete access to Express Scripts' books, records, and dispensing data. Indeed, an essential part of the successful operation of the Formulary & UM Enterprise alleged herein depended upon secrecy.
- 725. It was foreseeable to Express Scripts and members of the Formulary & UM Enterprise that Plaintiffs would be harmed when they engaged in the fraudulent scheme that forms the common purpose of the Formulary & UM Enterprise and the pattern of racketeering activities alleged herein.
- 726. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.
- 727. The Formulary & UM Enterprise members' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injury in its business and property.
- 728. The Formulary & UM Enterprise members' pattern of racketeering activity logically, substantially and foreseeably has caused an opioid epidemic. Plaintiffs were injured by

the Formulary & UM Enterprise's pattern of racketeering activity and the opioid epidemic that its members created through their actions.

- 729. Members of the Formulary & UM Enterprise knew that the prescription opioids at the center of their pattern of racketeering activity were extremely dangerous, highly addictive, prone to diversion, abuse and misuse, and often cause overdose and death. They were also aware that placing those drugs in favorable formulary positions with UM controls in place would grow the market for prescription opioids through increased prescribing, dispensing and sales. They were also aware that the growth in prescribing, dispensing and sales would be driven, in large part, by oversupply, addiction, and misuse and abuse. Members of the Formulary & UM Enterprise also knew that the oversupply, addiction, misuse and abuse would result in the writing of illegitimate prescriptions about which Express Scripts' mail-order pharmacies would need to conduct due diligence or refuse to fill.
- 730. Nevertheless, members of the Formulary & UM Enterprise engaged in a scheme of deception, which utilized the mail and wires as part of their fraud, in order to increase prescribing of prescription opioids, and providing the Opioid Enterprise Manufacturers' drugs unfettered formulary access without limits from UM in Express Scripts' standard offerings. Members of the Formulary & UM Enterprise also engaged in felonious possession and dispensing of controlled substances by filling prescriptions without performing due diligence and failing to refuse to fill prescriptions, thereby providing the Formulary & UM Enterprise with unfettered and illegal possession and dispensing by Express Scripts' mail order pharmacies.
- 731. Plaintiffs were and continue to be damaged in their business and property by reason and as a result of Express Scripts' conduct of the Enterprise through the pattern and practice of

racketeering activity described herein, which was a logical, direct, foreseeable and substantial cause of the opioid epidemic.

- 732. The predicate acts and pattern of racketeering activity by the members of the Formulary & UM Enterprise has injured Plaintiffs in the form of substantial losses of money and property that were a logical, direct, and foreseeable substantial contributing cause of the opioid epidemic.
- 733. Specifically, Plaintiffs' injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include:
 - (a) Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
 - (b) Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
 - (c) Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
 - (d) Costs associated with emergency response by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
 - (e) Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
 - (f) Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' Communities;
 - (g) Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
 - (h) Losses caused by diminished property values in the form of decreased business investment and tax revenue.

- 734. Plaintiffs' injuries were proximately caused by Express Scripts' racketeering activities because they were a logical, substantial, and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic created by Express Scripts' conduct, Plaintiffs would not have lost money or property.
- 735. Plaintiffs' injuries were directly caused by the pattern of racketeering activities by the members of the Formulary & UM Enterprise.
- 736. Plaintiffs are most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.
- 737. Plaintiffs seek all relief as allowed by law, including, *inter alia*, actual damages; treble damages; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:
 - (a) Actual damages and treble damages, including pre-suit and post-judgment interest;
 - (b) Forfeiture as deemed appropriate by the Court; and
 - (c) Attorney's fees and all costs and expenses of suit.

THIRD CLAIM FOR RELIEF Negligence

- 738. Plaintiffs repeat, re-allege, and incorporate each and every allegation set forth in all other paragraphs of this Complaint as if fully set forth herein.
- 739. Express Scripts owes Plaintiffs a duty to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This includes a duty not to create a foreseeable risk of harm or injury.
- 740. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Express Scripts' conduct in selling, delivering, dispensing, promoting, and gatekeeping control of the supply of highly addictive and dangerous prescription opioids requires

a high degree of care and places them in a position of great trust and responsibility. Their duty cannot be delegated.

- 741. Express Scripts, by promoting prescription opioid over-use and by facilitating access to opioids through their standard formulary and utilization management offerings and their mail order pharmacies, set in motion a force that created an unreasonable and foreseeable risk of harm and peril for Plaintiffs and Plaintiffs' Communities.
- 742. Express Scripts also undertook and assumed a duty to create formulary and UM offerings based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. *See* Restatement (Second) of Torts § 324A Express Scripts represented to the public, as well as to their clients, that it was structuring formulary and UM offerings based on the health and safety of the public and the lives its clients insured, when in fact it was doing the exact opposite and doing it to maximize its own revenue in concert with the opioid manufacturers. Express Scripts knew, at the time it made these representations to the public and to its clients, that it would not base its formulary and its UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that they would structure, and were already structuring, formulary and UM offerings solely (or at least primarily) to increase profits to Express Scripts.
- 743. Express Scripts undertook to render services which it should have recognized (and in fact did know) were necessary for the protection of persons, including the public, residents of Plaintiffs' Communities, and Plaintiffs, and failed to exercise reasonable care in such a manner that Express Scripts increased the risk of harm to the public, Plaintiffs' Communities, and Plaintiffs. In so undertaking, Express Scripts assumed a duty to the public, Plaintiffs' Communities, and Plaintiffs.

- 744. Express Scripts had actual, or at the very least constructive knowledge, of the overuse and oversupply of opioids because of its access to claims and other data which it developed and maintained. Express Scripts also had the ability to curtail the overuse and oversupply of prescription opioids because of its unique gatekeeping function in the pharmaceutical supply chain. Yet, despite this knowledge and ability, Express Scripts refused and failed to take necessary and appropriate actions to prevent the harms which were the foreseeable consequence of their failures, actions and inactions.
- 745. Express Scripts, having facilitated and set in motion the over-use and over-supply of opioids, had a duty to use reasonable care to prevent and curtail the spreading of the opioid crisis.
- 746. Express Scripts breached this duty by failing to exercise reasonable care or skill with respect to their opioid-related conduct. Express Scripts made highly addictive prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger especially to patients who were using opioids for chronic pain not associated with active cancer, end-of-life or palliative care. Express Scripts knew or reasonably should have known that their breach would foreseeably cause harm to Plaintiffs and Plaintiffs' Communities.
- 747. Express Scripts was negligent in failing to abide by its duties to conduct itself with the requisite care and skill and faithfulness.
- 748. Express Scripts placed its profit motives above its legal duties and enabled, encouraged, and caused the over-supply and over-use of opioids within Plaintiffs' Communities.
- 749. Express Scripts is a highly sophisticated and knowledgeable actor in the health care marketplace, well informed of the highly addictive nature of prescription opioids and likelihood

of foreseeable harm to communities from prescription opioid addiction and diversion. Express Scripts breached its duties when it failed to act with reasonable care in its respective role, a role which positioned it to help abate the opioid epidemic if it elected to use its power for good, instead of profit.

- 750. A negligent and/or intentional violation of Express Scripts' duties poses distinctive and significant dangers to Plaintiffs and Plaintiffs' Communities.
- 751. At all times, Express Scripts had the ability and obligation to control the opioid access and utilization that led to this human-made epidemic. Express Scripts controlled and was responsible for the operation of the instrumentality of the harm in this case— its promotion of opioid over-use and facilitation of access to opioids through its formularies and UM offerings and its mail order pharmacies. Express Scripts failed to take appropriate precautions to avoid injuries to Plaintiffs caused by its failures, actions and inactions.
- 752. Express Scripts knew or in the exercise of reasonable diligence should have known under the circumstances of this case that the harms suffered by the Plaintiffs and Plaintiffs' Communities were the reasonably foreseeable consequences of Express Scripts' failures, actions and inactions.
- 753. Express Scripts' conduct also foreseeably created a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Express Scripts' deceptive and improper conduct is not only an explosion of prescription opioids on the black market, but also—predictably and foreseeably—a marked increase in the availability of heroin and synthetic opioids.
- 754. The health, safety, and welfare of Plaintiffs' Communities, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great

public interest and legitimate concern to the citizens and residents of Plaintiffs' Communities and to Plaintiffs. It was reasonably foreseeable to Express Scripts that the burden of the opioid crisis would fall on communities and entities like Plaintiffs' Communities in the form of social and economic costs. Express Scripts' negligence was a substantial factor in producing harm to Plaintiffs and Plaintiffs' Communities.

- 755. Express Scripts controlled and was responsible for the operation of the instrumentality of the harm in this case its promotion of opioid over-use and facilitation of access to opioids through their formularies and utilization management and mail order pharmacies. Express Scripts failed to take appropriate precautions to avoid injuries to Plaintiffs and Plaintiffs' Communities caused by Express Scripts' failures, actions and inactions.
- 756. As a direct and proximate result of Express Scripts' negligent conduct, Plaintiffs have incurred, and will continue to incur, excessive costs to treat the opioid epidemic in each Plaintiff's respective Community including, but not limited to, increased costs of police, emergency, health, prosecution, corrections, rehabilitation, and other services. These costs are over and above Plaintiffs' ordinary public services.
- 757. As a proximate result of its failures, Express Scripts has caused Plaintiffs to incur excessive social and economic costs related to responding to the opioid crisis. These costs include but are not limited to, increased policing, medical, fire, and court services, lost tax revenues and lost productivity.
- 758. Express Scripts' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

- 759. The injuries and damages to Plaintiffs would not have happened in the ordinary course of events had Express Scripts exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business in the sale, delivery, dispensing, promotion, and gatekeeping control of opioids.
- 760. Plaintiffs are asserting their own rights and interests and Plaintiffs' claims are not based upon or derivative of the rights of others.
- 761. Plaintiffs are entitled to recover compensatory damages as a result of Express Scripts' negligence, in an amount to be determined at trial.
- 762. Express Scripts' conduct was carried out with actual malice toward Plaintiffs and a conscious, reckless and outrageous indifference to the health, safety and welfare of others. They had actual, subjective awareness that, viewed objectively from their viewpoint at the time, their conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Express Scripts knew of the dangerous and addictive nature of prescription opioids and also knew the risks associated with the oversupply and diversion of such drugs. Yet it nevertheless proceeded with the conscious indifference to the rights, safety, or welfare of Plaintiffs and Plaintiffs' Communities by and through their conduct described herein. For this reason, Plaintiffs seeks to recover punitive/exemplary damages.
- 763. As a result of Express Scripts' intentional, willful, wanton and/or reckless conduct described herein, Plaintiffs seek all legal and equitable relief as allowed by West Virginia law, including, *inter alia*, compensatory damages, including, *inter alia*, compensatory damages, treble, punitive, exemplary and/or otherwise enhanced damages to the full extent available under state law, and all damages allowed by law to be paid by Express Scripts, attorneys' fees and costs, preand post-judgement interest, and such other relief as this Court deems appropriate.

FOURTH CLAIM FOR RELIEF

Civil Conspiracy

- 764. Plaintiffs repeat, re-allege, and incorporate each and every allegation set forth in all other paragraphs of this Complaint as if fully set forth herein.
- 765. Express Scripts' conspiracy and acts in furtherance thereof are alleged in detail above in this Complaint, including without limitation, all paragraphs addressing Express Scripts' agreements and concerted action with the opioid manufacturers, all paragraphs addressing Express Scripts' enterprises, and all racketeering counts. These allegations are specifically incorporated herein.
- 766. Express Scripts' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including without limitation, all paragraphs addressing Express Scripts' agreements and concerted action with the prescription Opioid Manufacturers, all paragraphs addressing Express Scripts' enterprises, and all racketeering counts. These allegations are specifically incorporated herein.
- As alleged in these paragraphs and throughout this Complaint, Express Scripts and the prescription opioid manufacturers engaged in concerted action to accomplish an unlawful objective, or to accomplish a lawful objective by unlawful means: the unfettered sale and dispensing of vast quantities of prescription opioids in each Plaintiff's respective Community without regard to patient safety, the impact on the community, or their obligations and duties under federal and state law. Express Scripts acted pursuant to an agreement, or meeting of the minds, with that common intent and purpose.
- 768. Express Scripts and its co-conspirators committed numerous acts in furtherance of the conspiracy, as detailed throughout this Complaint. Express Scripts and their co-conspirators, acting in concert and/or in conspiracy with one another, intentionally, unlawfully, unlawfully

and/or recklessly manufactured, marketed, distributed, and sold prescription opioids that Express Scripts knew, or reasonably should have known, would be improperly diverted, causing widespread distribution of prescription opioids in Plaintiffs' Communities. This resulted in, without limitation, addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs' Communities at the expense of Plaintiffs, a higher level of fear, discomfort and inconvenience within Plaintiffs' Communities, and direct and indirect costs to Plaintiffs.

- 769. Specifically, prescription opioid manufacturers contracted and agreed with Express Scripts, to coordinate unfettered formulary placement with no or limited UM measures regarding each prescription opioid drug on Express Scripts' standard offerings, such that there would be as little an impediment as possible to opioid prescribing and dispensing. These contracts relied on an underlying fraudulent scheme designed to ensure unfettered access to PBM formulary offerings. The opioid manufacturers understood that Express Scripts was going to operate on a fundamentally fraudulent basis. As alleged more fully herein, even though Express Scripts promised its clients it would take actions that would ensure the safety of opioid prescribing and dispensing, Express Scripts had no intention of taking action regarding the prescription opioid manufacturers' branded and generic drugs that would have ensured safety, because those actions would have dramatically reduced their receipt of rebates, revenue from opioid dispensing, and other fees. At the same time, Express Scripts operated its mail-order pharmacies in such a way that they did not stop obviously illegitimate prescriptions from being dispensed.
- 770. As set forth in this Complaint, Express Scripts and the opioid manufacturers committed numerous overt acts to further the conspiracy's objectives that were unlawful under federal and/or West Virginia law.

- 771. At all relevant times, Express Scripts was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids.
- 772. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Express Scripts committed overt acts in furtherance of its conspiracy.
- 773. As an intended result of the intentional wrongful conduct as set forth herein, Express Scripts has profited and benefitted from the opioid epidemic it caused, thus harming Plaintiffs.
- 774. As a direct and proximate result of Express Scripts' and its co-conspirators the opioid manufacturers' intentional wrongful conduct, Plaintiffs have incurred substantial costs including, but not limited to, law enforcement action for opioid-related drug crimes, for addiction treatment, and other services necessary for the treatment of people addicted to prescription opioids, and the other harms alleged herein. Similarly, abating the vast societal harms Express Scripts and their co-conspirators caused will require extensive efforts and substantial resources. These costs and harms are addressed in more detail in the paragraphs addressing Plaintiffs' racketeering and public nuisance counts. These allegations are specifically incorporated herein.
- 775. Plaintiffs seek to impute liability for Plaintiffs' other claims on Express Scripts for the wrongful conduct of their co-conspirators, the opioid manufacturers, and to hold Express Scripts jointly and severally liable for that conduct.
- 776. Additionally, as discussed above, the conduct of Express Scripts was carried out with actual malice towards Plaintiffs and with a conscious, reckless and outrageous indifference to the health, safety and welfare of Plaintiffs, Plaintiffs' Communities, and the citizens of West Virginia. For this reason, Plaintiffs seek to recover punitive/exemplary damages.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment

- 777. Plaintiffs repeat, re-allege, and incorporate each and every allegation set forth in all other paragraphs of this Complaint as if fully set forth herein.
- 778. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Express Scripts has profited and benefited from the oversupply of opioids within Plaintiffs' Communities, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' Communities.
- Unjust enrichment arises not only where an expenditure by one party adds to the 779. property of another, but also where the expenditure saves the other from expense or loss.
- 780. Plaintiffs have expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Express Scripts' conduct. These expenditures have helped sustain Express Scripts' businesses.
- 781. Plaintiffs have conferred a benefit upon Express Scripts by paying for Express Scripts' externalities: the cost of the harms caused by Express Scripts' improper practices.
- Express Scripts was aware of these obvious benefits, and the retention of these 782. benefits is unjust.
- Plaintiffs have paid for the cost of Express Scripts' externalities and Express Scripts 783. has benefited from those payments. Because of their conscious failure to exercise due diligence in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids, Express Scripts obtained enrichment it would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

- 784. Express Scripts have unjustly retained benefits to the detriment of Plaintiffs, and Express Scripts' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.
 - 785. Express Scripts' misconduct alleged in this case is ongoing and persistent.
- 786. Express Scripts' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.
- 787. Plaintiffs seek an order compelling Express Scripts to disgorge all unjust enrichment to Plaintiffs; and awarding such other, further, and different relief as this Honorable Court may deem just.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter judgment in their favor against Express Scripts, jointly and severally, awarding all such relief the Court deems appropriate and just, including:

- (a) Abatement of nuisance;
- (b) Actual damages;
- (c) Treble or multiple damages and civil penalties as allowed by statute;
- (d) Punitive damages;
- (e) Disgorgement of unjust enrichment;
- (f) Forfeiture disgorgement, restitution and/or divestiture of proceeds and assets;
- (g) Attorneys' fees;
- (h) Costs and expenses of suit;
- (i) Pre- and post-judgment interest; and

(j) Such other and further relief as this Court deems appropriate.

XVI. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED: July 23, 2025

Respectfully submitted,

CITY OF WELLSBURG, BARBOUR COUNTY COMMISSION, BERKELEY COUNTY COMMISSION, GRANT COUNTY COMMISSION, HARDY COUNTY COMMISSION, JEFFERSON COUNTY COMMISSION, MINERAL COUNTY COMMISSION, MORGAN COUNTY COMMISSION, PRESTON COUNTY COMMISSION, POCAHONTAS COUNTY COMMISSION, TAYLOR COUNTY COMMISSION, TUCKER COUNTY COMMISSION, WEBSTER COUNTY COMMISSION, TOWN OF ADDISON, TOWN OF BELINGTON, CITY OF CHARLES TOWN, CITY OF GRAFTON, TOWN OF JUNIOR, CITY OF PHILIPPI, **CLAY COUNTY COMMISSION, LINCOLN COUNTY COMMISSION, MASON COUNTY** COMMISSION, MCDOWELL COUNTY **COMMISSION, MERCER COUNTY COMMISSION, MINGO COUNTY COMMISSION, MONROE COUNTY** COMMISSION, **PUTNAM COUNTY COMMISSION,** RALEIGH COUNTY COMMISSION, **SUMMERS COUNTY COMMISSION, CITY** OF LEWISBURG, VILLAGE OF BARBOURSVILLE, TOWN OF CHAPMANVILLE,

TOWN OF DELBARTON,
TOWN OF GILBERT,
TOWN OF HAMLIN,
TOWN OF KERMIT,
TOWN OF MATEWAN,
CITY OF MULLENS,
TOWN OF OCEANA,
CITY OF POINT PLEASANT,
CITY OF WELCH,
TOWN OF WEST HAMLIN, and
CITY OF WILLIAMSON, PLAINTIFFS,

By: /s/ *Paul T. Farrell, Jr.*

Paul T. Farrell, Jr., Esq. (WV Bar #7443) Michael J. Fuller, Jr., Esq. (WV Bar #10150)

FARRELL & FULLER, LLC

270 Muñoz Rivera Avenue, Suite 201

San Juan, Puerto Rico 00918 Telephone: 939-293-8244 Email: paul@farrellfuller.com

Email: <u>mike@farrellfuller.com</u>

/s/ Robert P. Fitzsimmons

Robert P. Fitzsimmons, Esq. (WV Bar #1212) Clayton J. Fitzsimmons, Esq. (WV Bar #10823) Mark A. Colantonio, Esq. (WV Bar #4238) Christine Pill Fisher, Esq. (WV Bar #13450)

FITZSIMMONS LAW FIRM PLLC

1609 Warwood Avenue Wheeling, WV 26003

Telephone: (304) 277-1700

Email: bob@fitzsimmonsfirm.com
Email: clayton@fitzsimmonsfirm.com
Email: christy@fitzsimmonsfirm.com

/s/ Anthony J. Majestro

Anthony J. Majestro, Esq. (WV Bar #5165) Christina L. Smith, Esq. (WV Bar #7509)

POWELL & MAJESTRO PLLC

405 Capitol Street, Suite P-1200

Charleston, WV 25301 Telephone: (304) 444-6082 Email: amajestro@powellmajestro.com
Email: asmith@powellmajestro.com

Counsel for Plaintiffs